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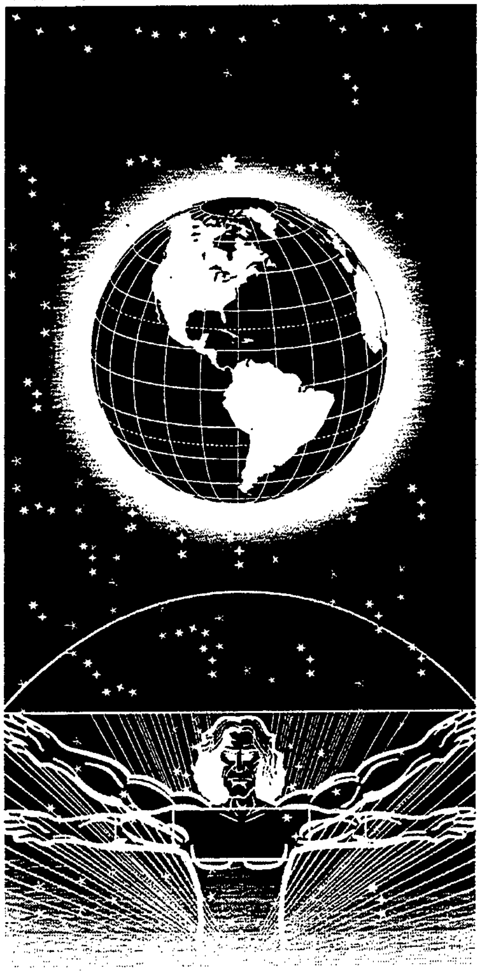

UNITED STATES AIR FORCE RESEARCH LABORATORY

HUMAN HEALTH RISK ASSESSMENT TEMPLATES (HHRATI)

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FOR THE DIRECTOR

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13. ABSTRACT *(Maximum 200 words)*
Human Health Risk Assessment Templates (HHRATs) are provided to aid the unfamiliar reader with the human health risk assessment (HHRA) process. The guidance follows the US EPA framework per the Superfund requirements for hazardous waste sites. The report provides an overview of the HHRA process. The appendix includes: tools assessment for fate and transport models, risk analysis and data handling; information resources; templates; and a process flowchart. The specific templates consist of: requirements; exposure scenarios; exposure assessment; chemical of concern (COC) data; dose-response evaluation; risk characterization; data gaps; and uncertainty assessment. The critical portion of the HHRA is the initial planning and coordination with various stakeholders such as regulatory agencies, public, industry, other governmental agencies and risk managers. The risk assessor should verify the "best practices" that are preferred by the stakeholders and integrate their use into the workplan. Once the risk assessment is underway, the risk assessor should assist the risk manager with communications requirements. The risk assessment can be conducted in a tiered process with each iteration providing more useful information that reduces the uncertainties.

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PREFACE

This technical report was prepared for the Armstrong Laboratory, Occupational and Environmental Health Directorate, Toxicology Division (AL/OET), Wright-Patterson AFB, OH by Operational Technologies Corporation (OpTech), Midwest Regional Office, 1010 Woodman Drive, Suite 160, Dayton, OH 45432. The government program manager was Lieutenant Colonel Larcom of AL/OET. The OpTech staff would like to acknowledge the AL/OET staff and in particular, Lt. Col. Larcom and Captain Weisman for their support as well as Ms. Connolly, the librarian for the Naval Medical Research Institute Detachment co-located at Wright-Patterson AFB, OH, for her assistance in literature retrieval.

LIST OF ACRONYMS/ABBREVIATIONS

*.DBF	Database file extension
*.DIF	Data interchange file extension
*.WKS	Lotus 123 spreadsheet file extension
*.WRK	Symphony spreadsheet file extension
*.XLS	Excel spreadsheet file extension
ACGIH	American Conference of Governmental Industrial Hygienists
AEHS	Association for the Environmental Health of Soils
AFCEE	Air Force Center for Environmental Excellence
AIHC	American Industrial Health Council
ARAR	Applicable or Relevant and Appropriate Requirements
ASCII	American Standard Character Format
ATSDR	Agency for Toxic Substance and Disease Registry
ASTM	American Society for Testing and Materials
CAS	Chemical Abstract Service
CDI	Chronic Daily Intake, (mg/kg-day)
CDM-2	Climatological Dispersion Model
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CHRIS	Chemical Hazards Response Information System
CLP	Contract Laboratory Program
COC	Chemical or Constituent of Concern
COPC	Chemical of Potential Concern
CRAVE	Carcinogen Risk Verification Endeavor
DoD	Department of Defense
DOE	Department of Energy
DOT	Department of Transportation
DQO	Data Quality Objective
E	Exposure Level
ECAO	Environmental Criteria and Assessment Office
EPA	Environmental Protection Agency
FS	Feasibility Studies
GIS	Geographic Information System
GKS	Graphic Kernel System
HAZWRAP	Hazardous Waste Remedial Action Program
HEAST	Health Effects Assessment Summary Tables
HHRA	Human Health Risk Assessment
HHRAT	Human Health Risk Assessment Template
HI	Hazard Index
HQ	Hazard Quotient
HSDB	Hazardous Substance Database
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
IRPIMS	Installation Restoration Program Information Management System
ISC2	Industrial Source Complex Model
K_{oc}	Adsorption Coefficient (soil adsorption related to organic content)
K_{ow}	Octanol water partition coefficient
LOAEL	Lowest Observed Adverse Effect Level
MKV	Moolgavkar-Knudson-Venson
MOC	Method of Characteristics
MSDS	Material Safety Data Sheet

NCEA	National Center for Environmental Assessment
NIOSH	National Institute for Occupational Safety and Health
NOAA	National Oceanic and Atmospheric Administration
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
NRC	National Research Council
NSDI	National Spatial Data Infrastructure
ODBC	Open Database Connectivity
OHMTADS	Oil & Hazardous Materials Technical Assistance Data System
PA	Preliminary Assessment
PB-PK	Physiologically -Based Pharmacokinetic
PDF	Probability Density Distribution Function
PERF	Petroleum Environmental Research Forum
PI	Principal Investigator
PRZM	Pesticide Root Zone Model
RAGS	Risk Assessment Guidance for Superfund
RBCA	Risk Based Corrective Action
RBSL	Risk Based Screening Level
RCRA	Resources Conservation Recovery Act
REL	Recommended Exposure Limit
RfC	Reference Concentration
RfD	Reference Dose
RI	Remedial Investigation
RITZ	Regulatory and Investigative Treatment Zone Model
RME	Reasonable Maximum Exposure
RTECS	Registry of Toxic Effects of Chemical Substances
SF	Slope Factor, $(mg/kg\text{-}day)^{-1}$
SI	Site Investigation
SSTL	Site Specific Target Level
STEL	Short Term Exposure Limit
SWMM	Storm Water Management Model
SYLK	Symbolic Link Format
TCL	Toxic Characteristic Leachate
TPHCWG	Total Petroleum Hydrocarbon Criteria Working Group
TPIPT	Technology Planning Integrated Process Team
TSR	Memory Resident Program
UCL	Upper Confidence Limit
USGS	United States Geological Survey
WASP5	Water Quality Analysis Simulation Model

HUMAN HEALTH RISK ASSESSMENT TEMPLATES (HHRAT)

INTRODUCTION

Background

The Toxicology Division of the Armstrong Laboratory's Occupational and Environmental Health Directorate provides the Department of Defense (DoD) with scientific analysis and technical support for their environmental, safety and occupational health programs. A primary support area is the evaluation and analysis of the criteria used for developing acceptable human risk and exposure at DoD facilities. The unit provides policy recommendations and strategies to fill risk assessment data gaps, proposes and conducts technical research such as toxicology studies on DoD materials of concern and assesses the human health risk of exposure to these materials.

This effort funded by the Toxicology Division is to provide a flexible human health risk assessment (HHRA) protocol to be used as a guidance and reference document. The document, including the templates, can be used to assist in characterizing health effects of individual chemicals. The guidance follows the Environmental Protection Agency (EPA) framework for assessing human health risk under Superfund at hazardous waste sites. As a guidance document, it can not address any definitive requirements imposed by the U.S. EPA or state/local regulatory agencies for specific sites. These requirements must be defined by the user in a preliminary assessment when meeting with stakeholders, including regulatory agencies, risk managers, citizens' groups and other interested parties.

Current Situation

As of 1993, the Federal Facilities Restoration Dialog Committee reported that 24,000 federal sites required remediation at an estimated cost of $400 billion. As of 1994, the DoD's portion was estimated to be $50 billion. Remediation costs tend to increase due to delays in implementation because of budget constraints, evolving political pressures and/or environmental regulatory requirements. The current HHRA paradigm for estimating risks at contaminated sites is based on conservative risk methodologies which may require extensive and costly remediation while not significantly reducing human or environmental hazards. Since 1986, the U.S. EPA has issued about two dozen risk assessment guidance documents (5,000 pages). The flexibility of these documents has been eroded by rigid applications that introduced several levels of conservatism to ensure that human risks were overestimated and not underestimated for the sake of public safety (Paustenbach, 1995).

A majority of the DoD hazardous waste sites are petroleum spills. In response to the costly remediation, the petroleum product manufacturers and DoD supported efforts to have a tiered risk-based corrective action (RBCA) process documented and presented as an American Society for Testing and Materials (ASTM) Standard (ASTM E-1739, 1995).

The objectives of the human health risk assessment template (HHRAT) are:

- To establish a generic methodology for guidance in performing a human health risk assessment of any hazardous material,
- To define the scope of information needed to perform a human health risk assessment, and
- To document best practices for estimating risks associated with exposures.

Format of the Report

Following an overview of the HHRA process in Sections I-IV (Introduction, Approach, Discussion, and Recommendations and Conclusions), a reference section (V) is presented. Appendices A through C consists of tool assessments for fate and transport, risk analysis, and data handling. Information resources are presented in Appendix D and the key appendix E contains eight templates addressing the HHRA process in detail. Appendix F contains flowcharts depicting the HHRA process. No prior risk assessment knowledge by the reader is assumed; therefore, references are provided to aid the reader.

APPROACH

Background

HHRA can be defined as the use of animal toxicology studies and human epidemiology data with exposure information to quantitatively predict whether a particular adverse response in the human population occurs. Four elements are normally used in a HHRA (NRC, 1983):

- Hazard Identification - evaluating available evidence on the presence and hazards of substances likely to cause adverse effects.
- Dose-Response- determining the degree of the effects at different doses,
- Exposure Assessment - estimating the magnitude, duration and frequency of human exposure to pollutants of concern and the number of people exposed via different pathways, and
- Risk Characterization - combining the information from the first three elements to estimate the risk associated with each scenario considered and to present uncertainty analysis to the risk managers.

Literature Review of Best Practices

A literature review confirms significant advances in HHRA approaches have been made. Physiologically based pharmacokinetics (PB-PK) modeling allows use of rodent studies to predict how the human will respond to a chemical (Andersen *et al.*, 1991). PB-PK modeling quantitatively accounts for the differences in the rodent and human by considering bodyweight, metabolic capacity and products, respiration rate, blood flow, fat content and other parameters. To date, PB-PK models have been developed and validated for at least 40 compounds including DoD compounds of concern such as methylene chloride, trichloroethylene, benzene,

benzo(*a*)pyrene, chromium, lead, PCBs, toluene and xylene. However, to date, the regulatory agencies have depended on safe levels of exposure to air, water and soil contaminants by using statistical models with conservative uncertainty factors in lieu of using PB-PK models to reduce the uncertainty. In the future, PB-PK analysis and other biologically-based models such as Moolgavkar-Knudson-Venson (MKV) could be used instead of the traditional statistics-based models for dose-response assessments (Paustenbach, 1995).

Monte Carlo simulations have been proposed in public health risk assessments (Burmaster and Anderson, 1994). This technique allows the risk assessor to generate probability density functions or distributions for any test parameter and accounts for the variability in these parameters within a population. The Monte Carlo process can then produce a distribution which characterizes the population based on the underlying distribution of the input parameters. The risk manager is provided a probabilistic analysis such as the risk values for the 50th, 95th and 99th percentiles of the exposed population in lieu of a single point estimate. It should be pointed out that application of Monte Carlo analyses to human health risk assessments is still not routine as the regulatory decision-making process has relied on "point estimates" of exposure and risk. Regulatory agencies expressed concerns about the lack of guidance documents and policy as well as a lack of consensus on proper distributions for key exposure factors (Finley *et al.*, 1994).

U.S. EPA has been developing improved weight-of-evidence schemes to augment health risk assessment methodologies (U.S. EPA, 1994). The greater the weight-of-evidence, the greater the confidence in the derived conclusion.

Lessons Learned

The U.S. has been conducting HHRAs for the last 20 years and a literature review of best practices was conducted to aid in the development of this guidance document. Over 48 references were identified in the peer reviewed literature from 1995 through 1996 on risk assessment recommended methodology or practice. EPA has proposed guidelines for a revised approach to carcinogen risk assessment (U.S. EPA, 1996). Use of benchmark dose methods continue to be evaluated as a substitute for the No Observed Adverse Effect Level (NOAEL) approaches.

In those instances where existing published toxicity values demonstrate significant uncertainty, literature reviews must be performed. These reviews are iterative and must be updated throughout the process. To control cost one must refine the search protocol to focus on productive sources. The potential for excluding relevant sources always exists and must be balanced with search costs. Paustenbach gave an extensive critical review of the HHRA and provided a lessons learned table and discussion based on the four elements of risk assessment (Paustenbach, 1995). Table 1 is a summary adapted from his lessons learned review.

TABLE 1. LESSONS LEARNED IN HHRA

Hazard Identification	Dose-Response	Exposure Assessment	Risk Characterization
Do not consider all animal carcinogens (equally) as a serious human hazard	Present best estimates and bounds and not only upper bound of risk	Don't overemphasize risk on the maximally exposed individual	Understand a one in a million cancer risk is rarely a serious public health hazard
Consider "wt. of evidence" to evaluate data sets to classify a chemical as a carcinogen, reproductive toxicant, etc.	Consider risk estimates from several low dose models	Evaluate uptake (absorbed dose) for both 50% and 95% persons	Do not characterize low-dose modeling results as an actual increased risk - it is a plausible upper bound
	Conduct "reality check" on epidemiology data	Do not repeatedly use worse-case assumptions, consider Monte Carlo techniques when possible	Consider background levels of exposure when characterizing the degree of incremental risk
	Adjust for species biological differences using physiologically-based pharmacokinetic (PB-PK) models	Ensure proper statistical analysis of environmental data	Do not assume the solution to most env. hazards involves remediation or substitution with less toxic compounds
	Use low dose models to objectively rank carcinogens and not to predict actual cancer rate	Conduct sensitivity analysis to understand dose estimate fragility	Put risk estimates into perspective
	Know the limits of the low-dose models and use wt. of evidence to select best low dose method	Consider environmental fate when estimating exposure	Characterize risk using results of Monte Carlo analysis
		Validate the exposure estimate reasonableness	Conduct uncertainty and sensitivity analyses
		Consider biological monitoring to confirm exposure estimates	
		Consider indirect pathways of exposures	

Adapted from Paustenbach, 1995.

DISCUSSION

Human Health Risk Assessment Process

The HHRA process can be implemented in a tiered approach, involving increasingly sophisticated levels of data collection and analysis. The earlier tier assumptions are replaced with site-specific data and information in lieu of default values. The Tier 1 study will use default values with built-in safety factors to address uncertainty. The uncertainty and data gaps are addressed as you proceed to Tier 2 and Tier 3. Upon evaluation of each tier, the risk assessors and risk managers review the outcome and decide whether more site-specific analysis is warranted. The U.S. EPA and/or stakeholders would have to establish a procedure to permit departure from the default options (NRC, 1994).

ASTM E 1739 Approach

For petroleum release sites, the American Society for Testing Materials developed a standard which requires a site assessment to identify sources of the chemical(s) of concern, any obvious environmental impacts, any potential impacts on humans and potentially significant transport pathways (e.g., groundwater, air dispersion). The site assessment should include historical records review and a visual site inspection. The ASTM E 1739 Tier 1 evaluation is based on use of a look-up table containing screening level concentrations (known as Risk Based Screening Levels or RBSLs). The RBSLs were typically derived from the current reasonable maximum exposure (RME) levels and toxicological parameters recommended by the U.S. EPA. In the Tier 2 evaluation, the risk assessor can use RBSLs or introduce site-specific target levels (SSTLs), which are derived from site-specific conditions. The Tier 2 SSTLs can be derived from the same equations used to calculate the Tier 1 Risk Based Screening Level (RBSL), except site-specific parameters are used in the calculations. In the Tier 3 evaluation, SSTLs are used for both direct and indirect pathways using site-specific parameters. The Tier 3 evaluation may involve additional site assessment, probabilistic evaluations and more sophisticated chemical fate/transport modeling. The RBCA process recognizes that the allocation of limited resources (time, money, regulatory oversight, qualified professionals) to any one petroleum release site affects corrective action decisions at other sites. The ASTM E 1739 Standard points out that risk assessment is a developing science and that the RBSLs and SSTLs may vary by state due to regulatory requirements and the use of alternative scientifically based methods.

State of Science Practices

1. Since the publication of the National Research Council (NRC) 1983 risk assessment "Red Book", there has been an increased level of sophistication in risk assessment practices. The risk assessor must recognize and address more fully issues such as uncertainty, variability and aggregation (multiple chemical exposures) (NRC, 1994).

2. The NRC (1994) reported the following criticisms of current risk assessment practices:

- Default values used by the EPA are excessively "conservative"
- No recognition of synergistic effects of multiple chemical exposure
- Extreme variability of the human response to exposure is ignored
- EPA default options are rigid
- Block the use of chemical-specific data
- Impede research on novel approaches
- EPA has not defined exposure assessment with clarity
- EPA has not specified how to characterize populations and subpopulations
- The NOAEL-safety factor approach for noncancer hazards is not scientifically rigorous
- Some believe with the existing state of science that credible risk assessment is not possible
- No good mechanism to resolve disputes over risk assessment results
- Some state governments want more preliminary planning to better address limited resources allocation

Despite the criticism of EPA's rigidity, the press has recognized the "politicizing" of the risk assessment process with the introduction of pseudo-scientific practices in various litigations which further complicate the scientific uncertainties.

Tiered HHRA Process

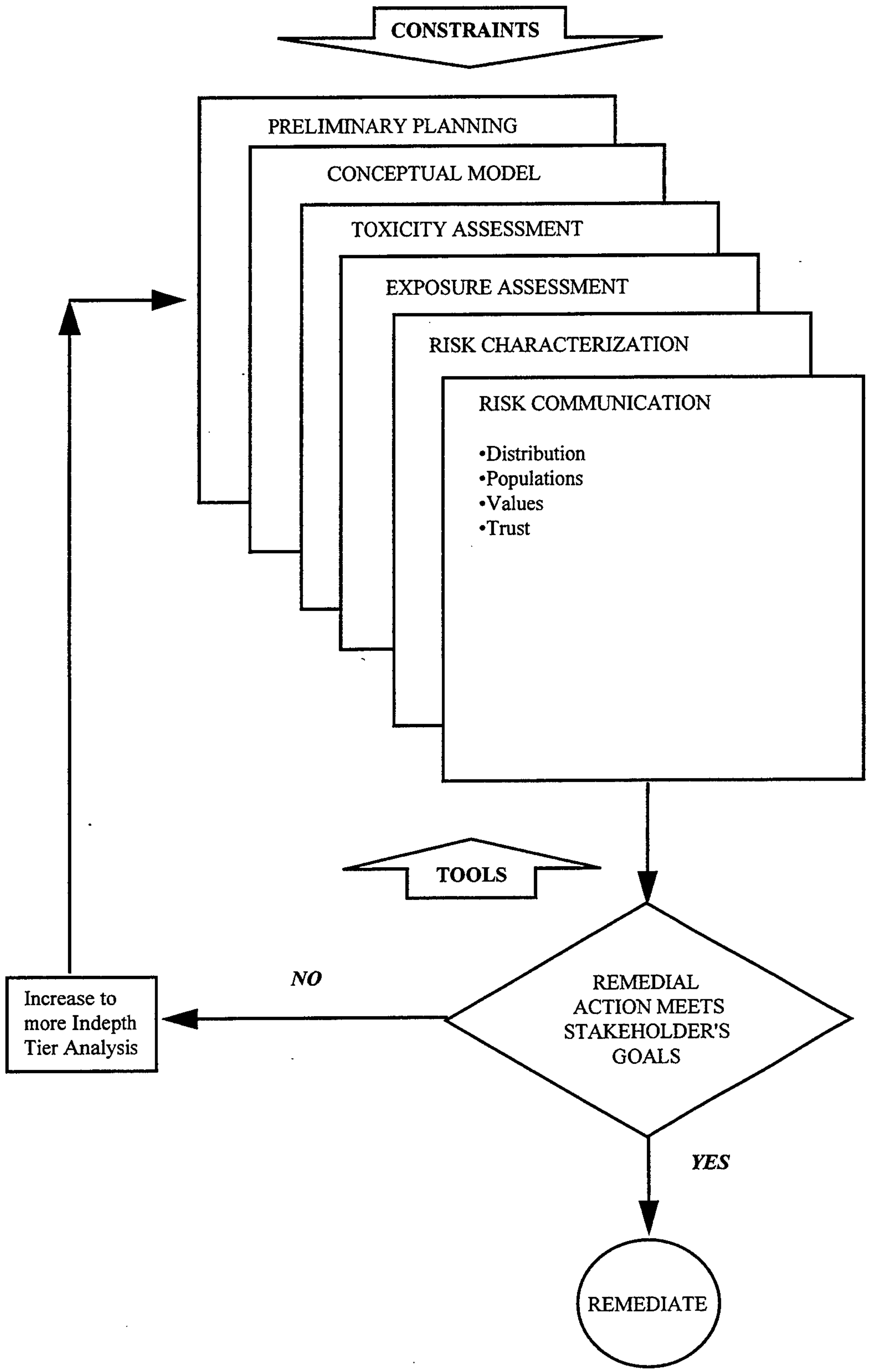
Approaching the risk assessment process as a single pass exercise has led to delayed findings and rework due to false assumptions. An iterative process meeting the procedural dictates of the EPA Risk Assessment Guidance for Superfund (RAGS) (U.S. EPA, 1989a) and yet adopting the multipass framework of the ASTM 1739-95 is projected to be more efficient and support stakeholder communication. A representation of the process is found in Figure 1. Elements of this process are supported by the templates and tool analyses located in the appendices.

Preliminary Planning

1. Stakeholders and Regulatory Status - Stakeholders or risk managers include the decision officials within the federal, state and local agencies with jurisdiction over the resources in questions (e.g., U.S. EPA, State EPA), the general public, special interest groups and others. The stakeholders should convey what they expect from the risk assessment, provide interpretation of pertinent regulations, define the scope of risk assessment, acceptable level of uncertainty, the environmental values of concern and availability (i.e., funding and manpower) resources. Stakeholders are faced with the reality of conflicting interests.

2. Risk assessor role - The risk assessors provide the scientific characterization of the targeted resources, present the current understanding of the stressors and the potential sources that may effect receptors, provide insight into the appropriate scale and focus of the risk assessment, consider the stakeholder values, specify what data is available, assess its uncertainty and specify what additional data is needed.

FIGURE 1: HUMAN HEALTH RISK ASSESSMENT PROCESSES



3. Interaction of stakeholders and risk assessor - This interaction is needed to define planning objectives, select management goals, determine the extent and complexity of the risk assessment in terms of the constraints and acceptable levels of uncertainty. A planning document should summarize why the risk assessment was initiated, define the management goals and technical approach for the risk assessment, establish the extent and complexity of the risk assessment and delineate the resources.

4. Workplan - As part of the hazard identification element, selection of chemicals of concern or "indicator compounds" must be undertaken. It is important to establish data quality objectives (DQOs) that specify the quality and quantity of data needed to support risk managers' decisions. A critical part of the workplan is the sampling strategy. Key considerations (U.S. EPA, 1990) for the sampling strategy are:

- What are the uses of the data and who will use them?
- Should the data be collected, analyzed and validated using the EPA Contract Laboratory Program (CLP) or is some other protocol more appropriate or legally defensible?
- What type of sampling program is appropriate - purposive, biased toward "hot spots", random, systematic or a combination of these types?
- How many samples are needed for significant results and what analytes should be tested?
- Are sample sites close to potential exposure points?
- Is the analytical method's detection limit sufficient to meet applicable or relevant and appropriate requirements (ARARs) such as drinking water maximum contaminant levels (MCLs)?
- Are background and off-site samples specified? How many and where?

Conceptual Model

1. Site Assessment Information - Identification of chemicals of concern (COCs) should begin with a review of the site history (i.e., chronology of land use) and activities. This data will provide insight to what chemicals can be expected to be found on-site and may provide insight into COC sources from other sites nearby. Data sets for the air, water, soils and subsurface concentrations of chemicals such as volatile organics, petroleum hydrocarbons, chlorinated solvents, pesticides, transformation products and metals should be reviewed. From a multitude of chemicals of potential concern, indicator chemicals can be selected on the basis of:

- Toxicity (cancer slope factor or reference dose),
- Concentration in media compared with background levels,
- Concentration in media versus standards and criteria (i.e., risk-based screening levels which are used in several regions such as Region III),
- Frequency of detection (could ignore if less than 5%), or
- Fate and Transport characteristics (high solubility implies off-site migration, transformation, persistence [half-life], bioaccumulation and bioconcentration factor).

2. Information sources to define site characteristics, identify potential exposure pathways and exposure points and help in determining data needs (including modeling) could be: Remedial Investigation/Feasibility Studies (RI/FS) reports, Preliminary Assessments/Site Investigations (PA/SI) and Hazard Ranking System documentation, list site inspections, photographs, records

on removal actions taken at the site and information on amounts of hazardous material disposed.

3. Potentially Complete Pathways (Scenarios) - In the conceptual model, all pathways are proposed that could potentially result in exposure. As the risk assessment is conducted, pathways that are not completed are removed from the model. A pathway is complete if all of the following conditions are met:

- A source with a release mechanism such as volatilization, leaching, surface runoff
- A transport medium for the released constituent such as air or drinking water
- Human receptor and potential point of contact with the contaminated medium
- Intake or uptake routes at the point of contact by the receptor such as inhalation, ingestion, and dermal adsorption

For example, shallow groundwater is normally not used for drinking water and would not represent a complete pathway unless extremely shallow wells were know to exist in that area. Some regions have adopted more constraining assumptions and need to be understood by the risk assessor.

4. As a best practice, conceptual model review by the risk managers, especially the governmental agency program manager, may be useful to assure that the individual conducting the risk assessment is working in agreement with stakeholders.

Toxicity Assessment/Dose-Response Assessment

1. Once the COCs are selected, the toxicity information on these compounds is collected and evaluated. The exposure periods for these toxicity values must be estimated to determine whether a subchronic or chronic toxicity value is most appropriate. Toxicity values are separated based on carcinogenic and noncarcinogenic effects. In the future, toxicity values will consider reproductive effects and other non-classical endpoints. The best data for human assessment is epidemiological information. However, very few chemicals have been assessed with well-conducted epidemiological studies. Therefore, extrapolation of animal studies is done to estimate the human response to COCs. Animal studies done with similar results across sexes, strains, species and different routes of exposure give confidence that similar adverse effects will be observed in human. When toxicity values were developed and what uncertainties existed in the data sets provide insight into the robustness of the current published values. The published values can and do change. With multiple COCs, the mechanism of injury and target organs yield insight into synergistic, additive, or independent insults.

2. The U.S. EPA has a prescribed hierarchy for toxicity data sources:

- EPA's Integrated Risk Information System (IRIS),
- EPA's Health Effects Assessment Summary Tables (HEAST),
- EPA Environmental Criteria and Assessment Office (ECAO), Cincinnati OH (513-569-7300).

Favorable internal peer reviews across the Agency will yield confidence that any resulting analysis will be accepted.

3. Other information sources could include:

- Agency for Toxic Substance and Disease Registry (ATSDR) toxicological profiles,
- TOXNET Databases such as Hazardous Substances Database (HSDB), Registry of Toxic Effects of Chemical Substances (RTECS),
- Open literature review.

4. The toxicity values for noncarcinogenic effect (Reference Doses or RfDs) are available from the above sources. The selection of a RfD is based on the exposure period. Chronic RfDs are used for exposures exceeding seven years and subchronic RfDs for exposures between two weeks and seven years. One- and Ten-Day Health Advisories are available for oral exposure periods less than two weeks. Depending on the exposure situations, more than one toxicity value may be necessary to assess the potential noncarcinogenic effect. Additionally, the Agency for Toxic Substance and Disease Registry (ATSDR) has published minimum risk levels (MRL) for 46 inhalation and 67 oral hazardous substances as of Dec 1994. In specific instances, they departed from using default uncertainty factors when site specific information was available (Mumtaz *et al.*, 1995).

5. EPA has assigned "slope factors" for carcinogenic chemicals and the above noted sources are used to find these cancer potencies. The EPA has used the linearized multistage model as the default model for calculating quantitative estimates of low-dose carcinogenic risks from animal data. It is a flexible statistical model that can describe a linear as well as a non-linear low-dose slope of the dose-response curve (Crump, 1996).

6. For toxicity values lacking EPA-derived values, a technical documentation or justification of the method of derivation should be included in the appendix of the risk assessment report. Coordination with the ECAO early in the process is recommended to avoid any duplication of effort. Particular attention should be placed on recent peer reviewed assays relating to reproductive or development endpoints, neurotoxic endpoints or endocrine disruption.

7. Uncertainty discussion of the toxicity values should be included in the report. The discussion should include a brief synopsis on:

- The use of high dose observed effects data to assess low dose expected exposure,
- The use of subchronic or acute dose response data to predict chronic exposure,
- The use of animal dose response data for human predicted effects,
- The use of either animal or human dose response data to predict sensitive human response, and
- The "weight of evidence" classification for the derived slope factors of the COCs.

It should be noted that EPA has used default values for uncertainty factors for noncancer risk assessment (e.g., extrapolation from animal to human data would result in an uncertainty factor of 10). Dourson *et al.* (1996) have presented science-based approaches where scientific data are available to substitute for the default values.

8. The following factors add strength to the evidence that a COC poses a hazard to humans:

- Similar effects across species, strains, sex, and route of exposure,
- Clear evidence of dose-response relationship,
- Plausible relationship among data on metabolism, postulated mechanism of action and the effect of concern,
- Similar toxicity exhibited by structurally related compounds, and
- Some link between the COC and the evidence of effect in human.

Exposure Assessment

1. Introduction - Exposure assessment is determining what the exposure or dose is and which pathways are complete or significant. The key aspects of this element are identification of potential receptor populations, evaluation of the exposure pathways and routes and the quantification of exposures.

2. Populations that may come in contact with COCs from a contaminated site include:

- Workers,
- Temporary workers,
- Visitors and trespassers,
- Area residents,
- Recreational visitors ,
- Sensitive subpopulations such as nearby schools, parks, hospitals, and
- Ecological receptors (fish, wetland, critical habitats, endangered or threatened or protected species).

3. Exposure pathways and routes - The pathway is the course that the COC takes from a source to the receptor via the environmental media (air via volatilization or particle generation, water via solubility). The route is how the transfer is made at the point of contact (inhalation, ingestion or dermal absorption). See Section III E 3. for criteria on determining whether a pathway is complete. ATSDR has published a framework to identify significant human exposures using site specific data (Mumtaz *et al.*, 1995).

4. COC Fate and Transport - Although it is likely that measured environmental media concentration values at the source are used directly in a risk screening, this normally results in an overestimation of the risk. This approach ignores in what media, in what form, in what concentration, for what duration and at what locations site-related COCs are likely to occur now and in the future. Modeling can be used to forecast the COC concentrations in various media, convey its transformation into less toxic forms or its attenuation or concentration by biodegradation or bioaccumulation. These models depend on input values for the COC concentration as well as rely on the physical and chemical properties of the specific COCs (e.g., K_{oc}, K_{ow}, solubility, vapor pressure, Henry's Law Constant, half-life, diffusivity, bioconcentration factor). Many of the models are available from the U.S. EPA; see Appendix C for more information.

5. Exposure quantification - For each pathway that is considered complete, the magnitude, frequency, and duration of exposure must be determined by either measurement or predicted

by modeling. Normally, it is not possible to measure each exposure point, so modeling is required to estimate exposure concentrations. The U.S. EPA's Exposure Factors Handbook (1990) should be used to find conservative default values and equations. Recommendations by the American Industrial Health Council (AIHC) Exposure Factors Source book (1994) provide statistical distributions on many of the factors. Where possible, site-specific information should be used.

6. Output - Normally, the average central tendency scenario and the reasonable maximum exposure (RME) scenario are reported. The average exposure would be based on the normal 50th percentile activities. The RME is defined by EPA as the 90th or 95th percentile exposure, implying that 5 or 10% of the potential receptor population are likely to exceed the RME's exposure or risk.

Risk Characterization

1. Risk characterization provides the probability of the exposed population experiencing an adverse effect, including cancer. The toxicity and exposure assessments are summarized and integrated into quantitative and qualitative risk expressions. Potential noncarcinogenic effects are characterized by comparing projected substances intakes with toxicity values. Carcinogenic effects are estimated probabilities that an individual will develop cancer over a lifetime of exposure. These cancer risks are projected from intakes and chemical-specific dose-response information. Uncertainties are incorporated into the risk characterization. Numerical risk expressions must be supplemented with explanatory text that interprets and qualifies the results.

2. Noncancer hazard quotient (HQ) = Exposure level or intake (E)/RfD, the reference dose. Note: E and RfD are expressed in the same units (mg/kg-day) and have the same exposure period (e.g., chronic, subchronic, or shorter term). For multiple routes or substances of similar toxic action (assuming no synergistic or antagonistic effects), a hazard index can be computed as:

$$\text{Hazard Index (HI)} = E_1/RfD_1 + E_2/RfD_2 + \ldots + E_i/RfD_i = \Sigma E_i/Rfd_i$$

HIs less than one are considered safe.

3. Quantification of carcinogenic effects is based on incremental risk and is estimated as:

Risk = CDI x SF, where
CDI = chronic daily intake averaged over 70 years (mg/kg-day) and
SF = slope factor $(\text{mg/kg-day})^{-1}$.

4. The incremental cancer risk is reported as a value such as 0.000003 or 3×10^{-6} or as 3 E -6 for three additional cases in an exposed population of one million. Although these risk estimates are an upper bound estimate, cancer risk estimates higher than 10^{-6} to 10^{-4} range are generally considered to be of regulatory concern. It is important to note that the lifetime risk of contracting some kind of cancer is one in three and the probability of death from that cancer is one in four (Kolluru *et al.*, 1996). This would imply that about 83,333 out of million people will die of cancer and that an incremental increase of one in a million will add 1 to this 83,333.

5. Uncertainty analysis - It is known that the uncertainty about the numerical results is generally large (i.e., on the range of at least an order of magnitude or greater). It is more important to identify the key site-related variables and assumptions that contribute most to the uncertainty than to precisely quantify the degree of uncertainty in the risk assessment. A qualitative/semi quantitative approach is generally used to aid decision-makers for a limited resources investment. Uncertainties sources include:

a. Site characterization - the environmental media concentrations range over orders of magnitude through time and space. As the number of samples increase, the confidence and costs increase. Most hazardous site analyses use the EPA Toxic Characteristic Leachate (TCL) parameters, whose limit of detection may not be sensitive enough to identify all constituents at a site. Also, the standard EPA CLP analysis may not include all COCs present at the site. Nominally, the 95% upper confidence limit (UCL) of the arithmetic mean is used for exposure assessment.

b. Toxicity assessment - the toxicological dose-response values are normally extrapolated from animal data and safety factors are incorporated to predict human effects. The EPA slope factors are 95% UCLs derived from a linearized multistage model. Normally, 100% oral absorption and bioavailability are assumed. Metals adsorbed to sediments or soils and many other compounds are not completely absorbed in the gastrointestinal tract. These factors tend to contribute to an overestimation of the risk whereas exclusion of contaminants from the risk assessment because of inadequate toxicity data could underestimate the risk.

c. Exposure assessment - there is significant uncertainty in the present and future population, exposure point concentrations, exposure timing, absorbed dose and bioavailability and other parameters. The use of the 95% UCL for the source term and default exposure factors representing 90th to 95th percentile and the typical convention of no allowance for dilution or degradation of the contaminants over time and distance tend to cumulatively overestimate the potential exposure. However, the lack of addressing more toxic transformation products can underestimate the future risk.

6. Sensitivity analyses are done to identify the important input parameters by adjusting their values to see the changes in the model response. For example, what is the risk outcome if the exposure period were doubled? For most risk assessments, the most sensitive inputs are the toxicity values (SF, and RfD) because of their orders of magnitude safety factors.

7. Probabilistic risk estimates incorporating a quantitative uncertainty and variability analysis can be done using Monte Carlo simulations. Instead of varying each parameter one at a time, the Monte Carlo simulations can vary all the inputs. As multiple simulations are done, the probability density distribution (PDF) for each variable can be generated. The resulting output distribution of the exposure or risk can be quantified to any specific probability such as the 50th or 95th percentile.

Risk Communication

The risk assessment team must present conclusions on the magnitude and kinds of risk at a site and include the major uncertainties affecting the risk estimates. To aid in the presentation of the information, techniques are available such as:

1. Geographic distributions - Graphic computer modeling can present both the environmental media concentration values and background values into Geographic Information System (GIS) layers that can be overlaid with the site map. Airborne, soil and subsurface (groundwater and sediment) concentration plumes can be shown in a spatial distribution and modeling can be accomplished to show temporal effects. Visual presentation of the data will greatly enhance communications with the risk manager, regulatory agencies and public.

2. Population distributions - Another possible GIS layer can be the current and future land use population distribution. Other GIS layers could show other sensitive receptors (wetlands or threatened and endangered species home range) or sensitive human populations (schools, day-care centers, etc.). This information could be used in deciding clean-up goals based on future land use.

3. Resistance to risk acceptance, value structures of stakeholders and mistrust among industry, citizens and government add complexity to risk communication. Objectives of participants vary widely and may not point to early conflict resolution. Both risk reduction and retribution goals may then exist.

RECOMMENDATIONS AND CONCLUSIONS

Use of Best Practices

Human health risk assessments practices are continuously being improved with use of emerging tools. For example, the use of PB-PK models will adjust for species physiological differences and help reduce the uncertainty of extrapolating animal effects data to humans. Monte Carlo simulations allow prediction of both exposure and risk using PDFs of the input parameters to forecast the output PDF and allow reporting of the central tendency measure and the 95% percentile to better quantify the risk estimate. Sensitivity analysis will demonstrate which input parameters are most critical and define the focus of any additional studies to reduce the uncertainty.

Impact on Outcome

The risk assessor should be aware of the best practices to decide whether it is prudent to incorporate them. In addition, the regulatory agencies may become accustomed to use of certain best practices and it is suggested the risk assessor discuss with the applicable regulatory agencies in the preliminary planning phase any preferred "best practices" to be implemented.

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APPENDIX A: FATE AND TRANSPORT TOOL ASSESSMENT

Introduction

The Human Health Risk Analysis Tool Assessment was undertaken to identify risk analysis, fate and transport, and data management tools that would be considered Best Practices for use within the Human Health Risk Assessment Template. Tools were identified for assessment based on the following criteria:

- Ability to run on a PC platform;
- Computer memory and hard drive space requirements;
- Integration of risk analysis with other tools;
- Data requirements and ability to manipulate variables;
- Ability to use/generate data usable by other modeling or data management tools;
- Validity of data output; and
- Ease of use.

Tool Identification

Approximately 2200 environmental software products available within the public domain and from commercial sources are identified on the Internet in the *1996 Guide to Environmental Software Products*, by the Environmental Software Cooperative (http://www.envirosw.com). This list of environmental software was reviewed for contaminant transport and risk analysis tools that fit the equipment criteria for assessment. Equipment criteria was set for this assessment as follows:

- Ability to run on a 486 PC computer;
- Requiring 100 Megabytes of hard disk space to load;
- Ability to run on a computer with 16 Megabytes of Random Access Memory (RAM); and
- Available on floppy disks or CD-ROM.

Information on tools that fit the criteria was collected from individual company or agency Internet home pages, published reports, and summary materials provided by companies or agencies. Demonstration copies of software were acquired when possible. If the entire executable program was available over the Internet, a copy was downloaded for evaluation and assessment.

Several reports have been published which also assessed different environmental models for risk assessment. Model evaluation criteria used in those reports have been assimilated into this assessment to the greatest degree feasible. Information from those reports relative to the criteria chosen for this assessment was also used to identify models for the evaluation matrix in this report. The evaluation matrix was used to identify models that the researchers felt would fill the need of the Government for human health risk assessment, would be readily accepted by users, and would exemplify the state of technology in risk assessment. Using the evaluation criteria, twenty contaminant transport and risk assessment models were chosen for full

assessment from the initial software tools identified through the *1996 Guide to Environmental Software Products*.

The models featured in this report were loaded onto a PC and run using default data sets to make this assessment. The models were evaluated based on data input requirements, ability to use/pass electronic data between models, ability for the user to vary the data, user knowledge requirements, ease of use, the ability to perform uncertainty analyses as part of the output, and the validity of the output. Most of the fate and transport models are DOS based models, designed and programmed to run from the DOS prompt. Those models that are identified as DOS based must be run without Windows or other memory resident programs (TSRs) loaded. Those that are DOS based but can run from a DOS window will allow the user to run the model without exiting Windows. Those models that are Windows based will run like other Windows programs by clicking on an icon. The models evaluated were identified as Tier I, II or III risk assessment models, based on the ASTM Standard for Risk Based Corrective Actions.

Fate and Transport Models

Fate and transport models are developed for modeling contaminant transport in media such as air, soil, surface water, or groundwater. Most transport models deal with only one or two of the media, only multimedia transport models deal with multiple media and contaminant movement between media. Most models identified through the *1996 Guide to Environmental Software Products* were developed by the EPA, United States Geological Survey (USGS), other Federal Government agencies, or were based on those models. The commercially available fate and transport models overwhelmingly have their basis in the models developed by or for the Federal agencies; the company offering the model has added a user interface such as Windows™, made minor changes to the model programming code, or developed an interface between different models which allows output from one model to be used as input into a model for another media.

The Federal agency models have gained acceptance by the regulatory and user communities because they were developed and validated under rigorous guidelines, and are supported by the Federal agencies. Due to this acceptance by the regulatory and user communities, this assessment of fate and transport models focused on those Federal agency models.

Air Fate and Transport Models

Model: SCREEN
Environmental Protection Agency - Center for Exposure Assessment Modeling
Type: Fate and Transport of Air Emissions

The SCREEN model estimates the maximum ground-level concentration for sources in simple flat or elevated terrains at a user specified distance from the point source of air emissions. The model includes an optional complex terrain screening procedure. The model also considers plume breakup due to cold air inversions, shoreline effects, and the effects of buildings on the plume. The model runs from the DOS prompt on a PC; however it can be effectively used by someone with very little expertise in DOS. The model will also run in a DOS window within

Windows™, allowing someone with no DOS experience to use the model. Data input requirements for the model are minimal, requiring only that the user answer some basic questions about discharge from the stack, basic topography of the area around the stack, and information about urban vs. rural land use downwind of the stack.

Output consists of concentration data at various distance intervals from the source, maximum 1 hour concentration beyond 100 meters from the stack, and maximum concentrations within a building cavity downwind from the source. The output can be viewed or printed in tabular format. The model is a good air contaminant concentration screening tool for a Tier I or II risk analysis for conservative, non specific contaminant transport.

Model: Climatological Dispersion Model (CDM-2)
Environmental Protection Agency - Center for Exposure Assessment Modeling
Type: Fate and Transport of Air Emissions

The CDM-2 model estimates a long-term (seasonal or annual) arithmetic average contaminant concentration at a ground-level receptor in an urban area. The model estimates quasi-stable pollutant concentrations in rural or urban settings using average emission rates from point and area sources and a joint frequency distribution of wind direction, wind speed, and stability. The model can account for the following: settling and dry deposition of particles; downwash due to buildings; area, line, and volume sources; and limited terrain adjustment. The model is appropriate for point or area sources, rural or urban areas, flat terrain, transport distances less than 50 kilometers, and long term averages from one month to one year or longer. The model can compute concentrations based on up to 200 point sources, 2500 area sources and an unlimited number of receptor locations.

The model runs under DOS, but the user can have trouble running the program under later versions of DOS. Data input requirements for the model are moderate to light, requiring that the user be familiar with meteorology, air emissions, topography of the area being modeled, and land use in the area. The user has a choice of seven dispersion parameter schemes. The model is not designed to be used by inexperienced users, but sample input files can be used to develop much of the information required for the model. Output data consist of concentration data at various distance intervals from the source and average concentration exposures over time; results can be viewed or printed in tabular format. Optional output includes point and area concentration roses and histograms of pollutant concentration by stability class. The model is a good air contaminant transport tool for a Tier II or III risk analysis.

Model: Industrial Source Complex Model (ISC2)
Environmental Protection Agency - Center for Exposure Assessment Modeling
Type: Fate and Transport of Air Emissions

The ISC2 model estimates the maximum ground-level concentration for a wide variety of sources associated with an industrial complex. The model can account for the following: settling and dry deposition of particles; downwash due to buildings; area, line, and volume sources; and limited terrain adjustment. The model can operate in both short-term (ISCST2) and long-term (ISCLT2) modes. Long term mode will provide average contaminant concentration at a receptor point over a year. The model is appropriate for multiple source

complexes, rural or urban areas, flat or rolling terrain, transport distances less than 50 kilometers, one hour to annual averaging times, and continuous air emissions.

The model runs under DOS, but can run in a Windows™ DOS window. Data input requirements for the model are heavy, requiring that the user be familiar with meteorology, air emissions, topography of the area being modeled, and land use in the area. The model is not designed to be used by inexperienced users, but sample input files can be used to develop much of the information required for the model. Output data consist of concentration data at various distance intervals from the source and average concentration exposures over time, and can be viewed or printed in tabular format. The model is a good air contaminant transport tool for a Tier III risk analysis.

Surface Water Fate and Transport Models

Model: SARAH2
Environmental Protection Agency - Center for Exposure Assessment Modeling
Type: Fate and Transport in Surface Waters

SARAH2 was developed to calculate the maximum allowable concentrations of contaminants discharged to land disposal or waste water treatment facilities based upon predicted exposure to humans or aquatic life. The surface water contamination pathways analyzed in SARAH2 include groundwater seepage of contaminants from land disposal facility or a lagoon, and discharge through a waste water treatment facility or lagoon. With a little experimentation on the part of the user, the model can predict the in stream concentrations from point or non-point source contaminants discharged into the stream.

The SARAH2 model runs under DOS but can be run in a DOS window. The model is an interactive, menu driven program with three default data sets that can be easily modified by a knowledgeable user. The analytical solutions for contaminant behavior in the stream near the facility allows for rapid, multiple calculations needed for good sensitivity analysis. The output from multiple runs can easily be manually input into a spreadsheet for sensitivity analysis by the user. The output from the model is minimal and very easy to understand. This model is good for a Tier II risk assessment fate and transport modeling run by the inexperienced user.

Model: Pollutant Routing Model (P-ROUTE) for Windows
Environmental Protection Agency -
Office of Water - Watershed Modeling Section
Type: Fate and Transport in Surface Waters

P-ROUTE was developed as a screening level contaminant routing model to calculate the downstream concentrations of contaminants discharged to a stream with multiple reaches. The concentration of the contaminant is calculated on a reach by reach basis using either low or mean flows. The surface water contamination can be derived from point or non-point sources with multiple sources identified by reach for all modeled reaches. The model is distributed with data on all water regions in the United States. The files also contain discharge permit information from the EPA Industrial Facility Discharger files. The model comes with multiple sample input and output files that an experienced user can easily modify. Data for the model

are displayed in easy to understand screens which allow the user to modify some of the data used by the model. Other data can be modified through editing the input file.

The PROUTE model is a DOS based model with a Windows™ interface the runs on a minimum PC configuration. The model is usable by inexperienced users and data input requirements are minimal. The output from the model is minimal and very easy to understand. A graphical tool is included with the model that shows contaminant concentrations by reach that are color coded to represent reaches that contain contaminant concentrations less than 0, from 0 to a user chosen threshold value, and those reaches with concentrations greater than the threshold value. This model can be used for Tier II risk assessment fate and transport modeling by the inexperienced user.

Model: Enhanced Stream Water Quality Model (QUAL2E) for Windows
Environmental Protection Agency - Center for Exposure Assessment Modeling
Type: Fate and Transport in Surface Waters

QUAL2E was designed to simulate conventional constituents (e.g., nutrients, algae, dissolved oxygen) under steady state conditions with respect to flow and contaminant input. The model can assist the user to determine the contaminant assimilative capacity of a stream by modeling dissolved oxygen and the various environmental factors which affect dissolved oxygen in addition to the primary contaminants of concern. The model calculates the downstream concentrations of non conservative contaminants discharged to a stream with multiple reaches from non-point sources. The model utilizes a first order decay mechanism, and external or internal stream source and sink terms that are temperature dependent in the mass balance equation.

The model comes with multiple sample input files that an experienced user can modify. Data for the model are displayed in 24 data input Windows screens which allow the user to modify most of the data used by the model. The model has utilities that allow the user to view input data in a graphical form that shows the stream reaches being modeled. Output from the model is detailed and also can be viewed in a graphical form using the same utilities. QUAL2EU is an upgraded version of the QUAL2E model that allows users to perform three types of uncertainty analysis: sensitivity analysis; first order error analysis; and Monte Carlo simulation.

The QUAL2E model is a DOS based model with a Windows™ interface the runs on a minimum PC configuration. The user is required to have some modeling experience and be familiar with information on stream reaches being modeled. This model is good for Tier II or III risk assessment fate and transport modeling by the experienced user.

Model: Water Quality Analysis Simulation Program (WASP5)
Environmental Protection Agency - Center for Exposure Assessment Modeling
Type: Fate and Transport in Surface Waters

WASP5, the Water Quality Analysis Program is a generalized modeling framework for contaminant fate and transport in surface waters. WASP5 was designed to model contaminant fate and transport in one, two or three dimensions. The model is designed to permit the user to study such problems as: biochemical oxygen demand, dissolved oxygen dynamics,

nutrients/eutrophication, bacterial contamination, and toxic chemical movement. WASP5 comes with two models that provide input to it: TOXI5 and EUTRO5.

TOXI5 combines a kinetic structure adapted from the EXAMS modeling system with the WASP5 transport structure and simple sediment balance algorithms. TOXI5 predicts dissolved and sorbed chemical concentrations in the bed and overlying waters. EUTRO5 combines a kinetic structure adapted from the Potomac Eutrophication Model with the WASP5 transport structure. This module predicts dissolved oxygen, carbonaceous biochemical oxygen demand, phytoplankton, carbon, chlorophyll-a, ammonia, nitrate, organic nitrogen, and orthophosphate in the bed and overlying waters. In addition, flows and volumes predicted by the link-node hydrodynamic model DYNHYD5 can be read and used by WASP5. Input files from other EPA models such as the Pesticide Root Zone Model (PRZM2) and the Storm Water Management Model (SWMM) can also read by WASP5.

WASP5 calculates the downstream concentrations of non conservative contaminants discharged to a stream with multiple reaches from point or non-point sources. The model requires that the user segment the stream and assumes that the hydrologic, benthic and sediment characteristics for each segment are the same. The model includes the following mechanisms for dealing with transport: advection and dispersion in the water column; advection and dispersion in the pore spaces; settling, resuspension and sedimentation of multiple types of solids; and evaporation or precipitation. The model needs data input on many variables, including loads, boundary concentrations, dissolved fraction, and particulate fraction of the contaminant.

The model comes with multiple sample input files that only an experienced user can modify. The model has a graphical viewer utility that will allow the user to view input data in a graphical form that shows the stream reaches. Output from the model includes time variable sediment and chemical concentrations for every segment of the stream being modeled. Output can also be viewed in a graphical form using the graphics utility. WASP5 is a powerful model that runs under DOS. The user is required to have heavy modeling experience and be familiar with information on the stream reaches being modeled. This model is useful for Tier III risk assessment fate and transport modeling by an experienced user.

Soil Fate and Transport Models

Model: Regulatory and Investigative Treatment Zone Model (RITZ)
Environmental Protection Agency, Office of Research and Development
Type: Fate and Transport in Soils and Vadose Zone

RITZ is a screening level model for simulation of unsaturated zone flow and transport of oily wastes during land treatment. The model considers a constant water flux and downward movement of the contaminant with the soil solution, volatilization and loss to the atmosphere, and (bio-)chemical degradation. The model incorporates the influence of oily contaminants upon the transport and fate of the contaminant, and is based on a series of analytical solutions. The treatment site modeled consists of a plow zone and a treatment zone. The model assumes that waste material is uniformly mixed in the plow zone, that the oil in the waste material is immobile, and that the soil properties are uniform from the soil surface to the bottom of the treatment zone. Furthermore, the flux of water is considered uniform throughout the

treatment site and throughout time, and hydrodynamic dispersion is insignificant and can be neglected. The partitioning of pollutant between the liquid, soil, vapor, and oil phases is described by linear equilibrium isotherms. Degradation of the pollutant and oil is described as a first-order process. The water content of the soil is related to the hydraulic conductivity.

RITZ is a DOS based program that can run in a DOS window. As input the model requires the properties of the chemicals and oil in the waste material, the soil properties of the treatment site, the management practices, and the parameters relevant to the environment of the site. RITZ is menu-driven and facilitates interactive data entry. The program produces graphical and tabular output. This model can be used for Tier II soil fate and transport model.

Model: Pesticide Root Zone Model (PRZM)
Environmental Protection Agency - Center for Exposure Assessment Modeling
Type: Fate and Transport in Soils and Vadose Zone

PRZM simulates one-dimensional vertical movement of multiple pesticides in the unsaturated zone within and below the root zone and incorporates parent/daughter relationships. PRZM2 links two subordinate models: PRZM and VADOFT. The model accounts for pesticide fate and transport in the crop root zone. The model includes the capability for soil temperature simulation, volatilization and vapor phase transport in soils, irrigation simulation, microbial transformation, and a method of characteristics (MOC) algorithm to eliminate numerical dispersion. PRZM is capable of simulating fate and transport of the parent compound and up to two daughter species.

VADOFT is a one-dimensional model which simulates the flow in the unsaturated zone. The user may make use of the constitutive relationships between pressure, water content, and hydraulic conductivity to solve the flow equations. The model may also simulate the fate and transport of two parent and two daughter products. The PRZM and VADOFT codes are linked together with the aid of a flexible execution supervisor which allows the user to build models tailored to site-specific situations. In order to perform exposure assessments, the code is equipped with a Monte Carlo pre- and post-processor.

PRZM is a DOS based program that can be run within a DOS window. Data input requirements for the model are extensive; however, the model includes sample input files that are well documented. The program produces tabular output that provides concentrations in the soil layer by compartment of soil one tenth (0.1) meter deep. This model can be used for Tier II soil fate and transport modeling by the experienced user.

Groundwater Fate and Transport Models

Model: AT123D
Environmental Protection Agency - Office of Toxic Substances
Type: Fate and Transport in Groundwater

AT123D was designed to simulate contaminant fate and transport in a uniform, steady-state groundwater aquifer. The model is a generalized, analytical one-, two-, and/or three-dimensional model for the estimation of transport of contaminants in groundwater. Three types

of contaminants, radioactive, chemical, and heat, can be modeled. The contamination can be derived from point, line, area, or volume sources for instantaneous, continuous, or duration releases. The model accounts for advection, dispersion, adsorption on particles in the aquifer, decay of the contaminant and generation of daughter products, and losses to the atmosphere. AT123D can also model aquifers with multiple boundary conditions. Flow velocity is assumed to be a constant rate, parallel, and uniform within the aquifer.

The AT123D model is a DOS based model that runs on a minimum PC configuration. The model comes with sample input and output files that an experienced user can easily modify. Data input requirements are nominal, but with some familiarity with the input file configuration, the less experienced user can make changes to the input file. The output from the model is tabular and can be imported into a contouring package such as Surfer. The model employs a simplistic analytical solution for groundwater flow, and therefore may not be useful for complex aquifers or complex groundwater flow situations. This model can be used for Tier I or II risk assessment fate and transport modeling by the less experienced user.

Model: EPA-VHS
International Groundwater Modeling Center
Type: Fate and Transport in Groundwater

EPA-VHS is an analytical solute transport model developed to predict maximum concentration of a contaminant at a distance downgradient from a source of continuous release. The model is a one-dimensional model for the transport of a conservative contaminant in a homogenous, isotropic aquifer with one-dimensional, horizontal, steady state flow. The model can only account for dispersion in directions perpendicular to the flow path. Continuous chemical contaminant input from a point source can be modeled to screen for concentrations downgradient of the release point. The model employs a simple analytical solution for groundwater flow, and is most useful as a screening tool.

The EPA-VHS model is a DOS based model that runs on a minimum PC configuration. The model can run in a Windows DOS window. The model comes with sample input data which are used as default values. Data input requirements are minimal, and with some familiarity with aquifer characteristics and contaminant concentration at the source, the less experienced user can run the model. The output from the model is displayed on the screen in a tabular format as concentration at the down gradient receptor point. This model can be used for Tier I risk assessment fate and transport modeling by the less experienced user.

Model: PLUME2D
International Groundwater Modeling Center
Type: Fate and Transport in Groundwater

PLUME2D is an analytical contaminant transport model developed to predict the concentration of a contaminant in a confined, steady state aquifer at a distance downgradient from the source of a continuous release. The model is a two- or three-dimensional model for the transport of a non-conservative contaminant in a homogenous aquifer with two-dimensional horizontal flow. The model can account for advection, dispersion, retardation, adsorption, and first order decay

of contaminants. The model employs an analytical solution for groundwater flow, and is most useful as a screening tool or a first-cut estimate of contaminant transport.

The PLUME2D model is a DOS based model that runs on a minimum PC configuration. The model can run in a Windows DOS window. Data input is interactive and data requirements are minimal, allowing the less experienced user to run the model. The output from the model is a grid of contaminant. This model can be used for Tier I or II risk assessment fate and transport modeling by the less experienced user.

Model: Method Of Characteristics Model (MOC)
United States Geological Survey
Type: Fate and Transport in Groundwater

MOC is a two-dimensional model for the simulation of non-conservative solute transport in heterogeneous, anisotropic confined aquifers. It computes time dependent changes in the spatial concentration distribution caused by convective transport, hydrodynamic dispersion, mixing or dilution from recharge, and reversible chemical reactions in equilibrium. The model can also take into account the effects of hydrodynamic dispersion, fluid sources and sinks, and divergence of velocity in the aquifer. MOC uses the method of characteristics to solve the solute transport equation. The program allows variable point sources of diffuse recharge or discharge, saturated thickness, transmissivity, boundary conditions, initial heads and initial concentrations, and an unlimited number of injection or withdrawal wells.

The MOC model is a DOS based model that runs on a minimum PC configuration. The model can run in a Windows DOS window. Data input is through a text file and input data requirements are heavy, allowing only the more experienced user to run the model. Sample input files are included with the model which can be manipulated by the experienced user. The output from the model is an extensive text file that lists concentrations by time steps. This model can be used for Tier II or III risk assessment fate and transport modeling by the experienced user.

Model: MODFLOW/MODPATH
United States Geological Survey, Water Resources Division
Type: Groundwater Flow / Contaminant Fate and Transport

MODFLOW is a modular model for the simulation of two-dimensional and quasi- or fully-three-dimensional, transient groundwater flow in anisotropic, heterogeneous, layered aquifer systems. The model is based on a block-centered finite-difference approach, using variable grid spacing in the x-, y-, and z-directions. Layers may be confined, unconfined, semi-confined, or convertible between the two conditions. The model includes modules for flow towards wells, through riverbeds, and into drains. Other modules handle evapo-transpiration and recharge. MODFLOW has the capability to implement first, second, and third type boundary conditions. It calculates heads, fluxes, and water balance. Various textual and graphic pre- and post-processors are available. MODFLOW is the most accepted and widely utilized groundwater flow model in the United States.

MODPATH is a post-processing package to compute three-dimensional pathlines based on the output from steady-state simulations obtained with the USGS MODFLOW groundwater flow model. The package consists of two FORTRAN 77 computer programs: 1) MODPATH, which calculates pathlines, and 2) MODPATH-PLOT, which presents results graphically. MODPATH uses a semi-analytical particle tracking scheme, based on the assumption that each directional velocity component varies linearly within a grid cell in its own coordinate direction. This assumption allows an analytical expression to be obtained describing the flow path within a given grid cell. Given the initial position of a particle anywhere in a cell, the coordinates of any other point along its pathline and time of travel between them can be directly computed. MODPATH-PLOT graphically displays results generated by the three-dimensional particle tracking program MODPATH. The USGS Graphic Kernel System (GKS) is linked to the MODPATH-PLOT source code to generate graphical output.

The MODFLOW model is a DOS based model that runs on a minimum PC configuration. Data input is through a text file and input data requirements are heavy, which allows only the more experienced user to run the model. Sample input files are included with MODFLOW which can be manipulated by the experienced user. Numerous courses are available to teach the user how to use MODFLOW. The output from MODFLOW is an extensive text file and a tabular file of steady state groundwater heads.

The MODPATH and MODPATH_PLOT programs have to be compiled using a Fortran-77 compiler readily available through commercial sources prior to being useful to the user. Input requirements for the MODPATH post-processor are minimal. Output includes particle pathlines, discharge point coordinates, and the total time of travel for each particle. Graphical output is obtained through the use of the MODPATH-PLOT program included with MODPATH. This model can be used for Tier II or III risk assessment fate and transport modeling by the experienced user.

APPENDIX B: RISK ASSESSMENT MODELS

Model: Crystal Ball
Decisioneering, Inc.
Type: Risk Analysis; Uncertainty Analysis

Crystal Ball is a graphically oriented forecasting and risk analysis tool developed as an Excel or Lotus 123 add-on. The model forecasts distribution and sensitivity of parameters used in a basic risk analysis calculation. The program is dependent upon user assignment of data distribution curves for each of the variables used in the risk analysis calculation. The program uses the distribution curves assigned by the user to develop an uncertainty analysis and a ranking of the variables by uncertainty. Output from the program includes the input distribution curves, the uncertainty forecast, and the ranking as a percentile of uncertainty. The program requires the user to have a strong knowledge of statistical analysis and distributions, as well as a reasonable level of risk assessment expertise. This is useful for Tier I or II risk analysis and uncertainty analysis for data output by other models.

Model: Risk Based Corrective Action (RBCA) 1.0
Groundwater Sciences, Inc.
Type: Risk Analysis

RBCA was developed to provide users with a spreadsheet based application to integrate risk based analysis in accordance with the ASTM Risk Assessment Standard into screening for corrective actions. RBCA is a macro sheet add on to Excel or Lotus 123 spreadsheets that uses target risk values to back calculate screening values for soil or gas. The model is input box driven and incorporates abundant default values for a Tier I assessment. The system includes air, groundwater, soil to groundwater, and soil to air fate and transport analytical algorithms with residential and industrial exposure scenarios.

Input data requirements for the model are minimal, and the user can change most of the default values easily. The system allows the user to add new data to the database easily and save those changes in the default database. Based on multiple sample data for a single location, the model will calculate mean concentrations and upper confidence limits for those concentrations. The output includes printed tables of input parameters, risk, screening levels, representative concentration of contaminants of concern and a comparison of those contaminant concentrations to screening levels. The system is moderately easy to use, requiring that the user navigate among multiple screens to input data. This model is useful as a Tier I or Tier II risk analysis tool.

Model: RIVRISK 3.0
Electric Power Research Institute
Type: Fate and Transport; Risk Analysis

RIVRISK was developed to provide fate and transport in river environments and risk to the aquatic ecology and human health from up to 16 exposure pathways due to contamination of surface water. The model considers contaminant concentrations from multiple sources including direct discharge into the river, contaminated groundwater seepage, runoff, and deposition into the river from aerial discharges. The model includes a database with physico-chemical and risk parameters on 122 organic and inorganic chemicals. Default data for the chemicals cannot be changed by the user. Data input requirements for the model are minimal, requiring only that the user know concentration data from the various sources of contaminant input into the system.

Output data, both concentration and risk, can be viewed or printed in tabular and graphical format. The graphs available include concentration vs. distance downstream from the source and hazard index vs. distance downstream from the source. Graphs default to inclusion of hazard index by pathway and as a total hazard. The model also performs uncertainty analysis on concentrations and human health risk via a Monte Carlo simulation with input of distributions by the user. Output for the uncertainty analysis includes graphical representation of the probability curve.

RIVRISK is a Windows™ program that utilizes easy to understand screens for choosing sources and exposure pathways, and for user data input/output. The model provides graphics screens for choosing sources and exposure pathways that the non-technical user can easily understand. Output data is presented in a spreadsheet format for ease of understanding by the user. The model is a good screening tool for a Tier II risk analysis, but the inability to change variables used in the transport model or risk analysis limits its usefulness in more detailed risk analysis.

Model Name: SmartRISK™ 2.0 for Windows
Pioneer Environmental Consulting
Model Type: Human Health Risk Assessment

SmartRISK™ is a risk assessment model that estimates the human exposure to contaminants based on concentrations at the receptor point. The software will allow the user to perform an exposure assessment, a toxicity assessment, or a risk characterization. The model can calculate risks based on multiple pathways, up to four different exposed individuals, and two exposure scenarios (RME and Alternate Exposure) identified for each run. SmartRISK does not calculate the concentrations at the receptor point; fate and transport models must be used outside of the risk assessment model to provide those concentrations. The user can create custom intake equations for every route of exposure. The user has access to a large default value database, but variables can be changed throughout the input data. Data input is accomplished through user friendly Windows™ screens and the program breaks data input into manageable compartments which are accessed through icons on the main screen. The default databases for use in the model can be changed by the user easily and the program will allow the user to save and backup those default databases.

Output from the model can be in text or graphical form. The output divides human health risk into cancer and noncancer risks. The output from the model can be viewed, printed, or exported to several commonly accepted file formats for import into other applications. The export file formats include a database file (*.DBF) format, a Microsoft Excel spreadsheet (*.XLS), a data interchange file (*.DIF), a symbolic link format (SYLK), a Lotus 123 spreadsheet (*.WKS), a Symphony spreadsheet (*.WRK), an ASCII text file, or an ASCII comma or quote delimited file. The ability to save the output to several different file formats maximizes the ability of the user to use the output from the model in many different ways, including numerical analysis and as input into a geographical information system. The model also provides uncertainty analysis through export of the risk report to Excel or Lotus 123 spreadsheet and a Monte Carlo simulation of data in the spreadsheet. This model would be useful in a Tier II or III risk assessment.

Model: Risk*Assistant for Windows 1.1
Hampshire Research Institute
Type: Risk Analysis; Fate and Transport in Air

Risk*Assistant models contaminant fate and transport in the air and risk to human health from numerous exposure pathways. Risk*Assistant comes with a Windows version of the Industrial Source Complex Model (Win-ISC2) from the Environmental Protection Agency. Win-ISC2 models the fate and transport of contaminant emissions from a wide variety of sources associated with an industrial complex, and provides the user with the maximum ground-level concentration of the emitted contaminants. The Win-ISC2 model is virtually the same as that above in the Air Fate and Transport Section. Risk*Assistant uses the output from the ISC2 model, or other concentration input from the user, to develop cancer risk estimates and hazard indices. Concentration data can be input manually by the user or imported from a spreadsheet or database as an ASCII tab-delimited file with the fields in a specified order.

The model includes a database with physico-chemical and risk parameters on a large set of organic and inorganic chemicals. The user can choose data from EPA or state governments that reside in the default database. Default data for the chemicals can be changed by the user. Data input requirements for the model can be minimal for a Quick*Risk assessment, requiring only that the user know the chemicals of concern, concentration data, the media of transmission and the exposure scenarios. The Quick*Risk function can be turned on or off through a button on the tool bar.

Output, both concentration and risk data, can be viewed or printed in tabular and graphical format. The output is well documented with notations, input data and output data grouped such that most users can easily understand. The graphs available include hazards, exposures, and risks to accompany the tables in the output. The model performs a user interactive uncertainty analysis of average daily dose, lifetime average daily dose, carcinogenic risk, or hazard index for non-cancer toxicity based on the routes of exposure or media.

Risk*Assistant utilizes easy to understand screens and windows for choosing sources and exposure pathways, and for user data input/output. The model utilizes a single base screen for choosing the data input screens needed in a logical and easy to understand method. The

model is a good screening tool for a Tier II risk analysis, but due to the flexibility to change most of the variables used in the assessment, the model can be useful as a Tier III risk analysis tool.

Model: RISKPRO
General Sciences Corporation
Type: Fate and Transport; Risk Analysis

RISKPRO incorporates EPA models to evaluate a toxic chemical's behavior when released to the air, soil, surface and groundwater. The software package also includes several databases required to run the models which contain information on toxic chemicals, climate, soil, and population distribution. The RISKPRO system is composed of a user interface which controls the fate and transport models. The simulation codes include programs for: estimating chemical data; air modeling (ISCLT and PTPLU); vertical transport of chemicals through the unsaturated zone (SESOIL); solute transport in groundwater (AT123D); predicting the fate of organic chemicals in surface water (EXAMS-II); and multimedia partitioning of chemicals (ENPART). The output of the models is concentrations at a receptor point which RISKPRO uses to develop a risk assessment. Concentration data can also be input into the risk assessment model manually by the user.

RISKPRO requires abundant inputs by the user and assumes a level of knowledge that requires an experienced risk assessor to use the model effectively. Since it runs under DOS, the user must also be familiar with common DOS commands. The program is hard to use because of the data input requirements when run with the fate and transport models included. When the user inputs concentration data from sources other than the models included with the risk assessment module, the risk assessment module is fairly easy to use and provides reasonably easy input screens. The output from the program is comprehensive and provides the user with risk to the receptor. The experienced user would be able to use this model for a detailed Tier III risk assessment.

APPENDIX C: DATA MANAGEMENT TOOL ASSESSMENT

Introduction

Data management tools are those tools that allow the user to analyze or visualize the distribution of spatially distributed data points such as contaminant concentrations in a stream or aquifer. These tools include databases, statistical analysis tools, graphical mapping tools, and geographic information systems. Database tools were excluded from this assessment since the majority of these tools are commercially available, and most users have one or more that they commonly use already. Many of the remaining data management tools are available through either commercial or governmental agencies.

Premier among the data management tools are those that allow the user to see a graphical representation of the data. Several of the EPA and USGS fate and transport tools have post-processors included in the model package that provide graphical output of the concentration data. In order to view the spatial distribution of the data, the user often needs to access a mapping tool. The geographical information system (GIS) was developed to tie line and area drawings, such as those developed with a computer aided drafting tool, to the database query capability. The EPA defines a GIS system as:

"A computer system designed to allow users to collect, manage, and analyze large volumes of spatially referenced and associated attribute data. GISs are used for solving complex research, planning, and management problems. The major components of a GIS are: a user interface, system/data base management capability, data base creation/data-entry capacity, spatial data manipulation and analysis package, and display generation function."

The EPA has begun the National GIS Program, which is responsible for developing and maintaining an Agency-wide support network; participating in the review and evaluation of new GIS related technologies; promoting the sharing of GIS data, applications, and expertise; coordinating with external organizations concerning GIS and related geographic data activities; and serving as a focal point for GIS issues within the Agency. The GIS Program was started because environmental data is mostly spatial data. In addition to the National GIS Program, the EPA also has the U.S. Environmental Protection Agency (EPA) Node of the National Geospatial Data Clearinghouse, a component of the National Spatial Data Infrastructure (NSDI). This node provides a pathway to find information about geospatial data available from the EPA..

Statistical Analysis Tools

Program: Geopack
United States Department of Agriculture, U.S. Salinity Laboratory
Type: Geostatistical Analysis of Spatial Data Variability

GEOPACK is a user-friendly geostatistical software system consisting of programs for conducting analyses of the spatial variability of one or more random functions. The system includes several statistical analysis options, such as mean, median, variance, standard

deviation, skew, and kurtosis. Maximum and minimum values can be determined for the selected data base. Programs are also included for linear regression, polynomial regression, the Kolomogorov-Smirnov test for distribution, and calculating various percentiles. Variogram programs allow determination of a sample variogram, the cross-semivariogram, or a semivariogram for combined random functions for a two-dimensional spatially-dependent random function. GEOPACK includes options to calculate ordinary kriging and cokriging estimators in two dimensions and their associated variance. Nonlinear estimators such as disjunctive kriging and disjunctive cokriging can also be determined.

Various graphics capabilities are included in GEOPACK such as linear or logarithmic line plots, contour plots, and block diagrams. The GEOPACK graphics programs produce intermediate quality output and are intended for quick and easy graphic illustrations. For the highest quality graphic output, GEOPACK can be interfaced with any user-define graphics package to develop custom graphics.

Program: GEO-EAS
U.S. EPA - Office of Research and Development,
Environmental Monitoring Systems Lab
Type: Geostatistical Analysis of Spatial Data

GEO-EAS is a collection of interactive software tools for performing two-dimensional geostatistical analyses of spatially distributed data. Programs are provided for data file management, data transformations, univariate statistics, variogram analysis (spherical, Gaussian, exponent and linear structure), cross-validation (for each of the variogram structure options), ordinary and simple, block and point kriging, contour mapping, post plots, and line/scatter graphs. Features include: hierarchical menus, informative messages, full-screen data entry/editing, on-screen graphical display of intermediate and final results and output to ASCII files and graphical metafiles.

Program: SiteGIS
GeoTrans, Inc.
Type: Geographical Information System Add-On

SiteGIS is a user-friendly, Windows-based software package for analyzing and presenting environmental data for soil and groundwater remedial investigations within a GIS framework. Groundwater (water level and water quality data), soil (quality) and geology (well data, borings, profiles) data bases are integrated with facility or site maps to prepare data visualization maps, time series charts and geologic sections. SiteGIS is an application for the MapInfo® desktop mapping package. For display of data, SiteGIS interfaces directly with Microsoft Excel (line graphs) and Golden Software Surfer (contours). As an MapInfo application, SiteGIS has access to various geographical presentation tools, an enhanced SQL querying language, and data exchange using DXF, DBF, XLS, and ASCII file formats. Options are available to translate data from ARC/INFO, TIGER and DLG formats.

Program: GIS\Key
GIS\Solutions, Inc.
Type: Geographical Information System

GIS\Key is an environmental data base management system with sophisticated report facilities and model interfacing. The system, specially designed for chemical, geological and hydrological data, integrates data evaluation and graphic reporting in a Windows environment. The system supports the digital line graph map series of the USGS, and interfaces with the MODFLOW three-dimensional flow model. Output includes various table formats and geologic cross-sections, boring logs, potentiometric maps, isopleth maps, structure maps, summary tables, hydrographs, and chemical time series graphs, among others. Input is supported by user-friendly forms. The MODFLOW grid can be designed using the graphic interface of GIS\Key and overlaying the base map with grid arrays.

Program: EPPL7
Minnesota Land Management Information Center
Type: Geographical Information System

Eppl7 is a raster based GIS designed for spatial data analysis and modeling. The system can display vector and raster data in multiple layers. The User can digitize vector data and the system rasterizes that data automatically. The system features over 32,000 rows and columns of vector and raster data coverages. Tied to the coverages is a database capable of up to 65,535 data classes. The system maximizes the efficient storage of data, thereby minimizing the storage space requirements for coverages. The EPPL7 system can translate data to and from most GIS formats. The program manual and tutorial have been revised to make the system easier to use for beginners and more powerful for the advanced user. Drivers included for display and printing devices are high resolution drivers. The system was designed to run on a 286 PC with minimum hard drive and RAM space. The system runs under DOS, but can run within a DOS window.

Program: ArcView
Environmental Systems Research Institute
Type: Geographic Information System

ArcView lets the user work with tables, maps, and charts, all in one application. With ArcView the user can use maps alongside traditional analysis tools, such as spreadsheets and business graphics, to get a completely new view of the data. The user can enhance maps with a wide range of image and raster formats including SPOT, TIFF, JPEG, and ERDAS IMAGINE. The user can also use ArcView software's multimedia links to add pictures, sound, and video to those maps.

It has been estimated that 80 percent of data have some geographic component such as a country name, state, ZIP Code, or street address. With ArcView, it's simple to link that data directly to maps via this existing geographic component. The user can map tabular data from Access, dBASE, Foxbase, ASCII, INFO, or any SQL or Open Database Connectivity (ODBC) database. ArcView's built-in SQL connect feature gives the user client/server database access that enables the user to add data residing almost anywhere in an organization to the map.

On one map, the user can integrate many different types of data including environmental, demographics, facilities, CAD, and images. ArcView has a powerful geocoding feature that automatically plots street addresses and other address data and helps the user manage incorrect or misspelled addresses.

ArcView GIS gives the user hundreds of new ways to query and analyze the data. The user can query the data according to location, content, proximity, and intersection; add data to maps, then find the geographic factors that drive trends and distributions; add different data layers, and then find locations at which particular characteristics coincide; or aggregate data geographically by summarizing it based on areas such as census tracts, states, or territories. The user will literally start to see things in a new light. Furthermore, the output from one analysis can be used as the input to the next analysis, enabling the user to create advanced geoprocessing applications.

ArcView allows the user to generate professional cartographic output from a desktop computer. ArcView provides automatic data-driven classifications, color ramps of data ranges, graduated symbols, chart symbols, standard deviations, normalization, and business graphics. ArcView comes with a huge selection of TrueType fonts and symbols. The user can use ArcView GIS with many types of output devices such as printers, plotters, and film output devices.

The maps that come with ArcView, and the additional map data available from ESRI and third parties, meet most needs. However, it's also easy to create basemap layers with ArcView. The user can add territories to a map, add new locations, or change the shapes of existing features such as roads or boundaries. The user can modify existing maps to meet the organizations exact needs; or if no maps currently exist, the user can create original maps quickly and easily. Maps can be edited on-screen with the mouse, or for more accuracy, using a digitizing tablet. The user can create proprietary mapping applications and custom user interfaces with Avenue, a built-in development environment designed specifically for GIS. With Avenue, the user can customize part or all of ArcView to meet the needs of end users. For example, the user might add a new tool to ArcView software's interface that performs a function specific to the organization, such as integration of fate and transport models into the system.

ArcView software's extensions make it easy to add new capabilities as and when the user need them. These extensions are plug-ins to ArcView that the user can load and unload at any time. ArcView GIS comes with a set of extensions. Several optional extensions are available, including the powerful analyst extensions, such as ArcView Spatial. ArcView software's optional Spatial Analyst includes a broad range of powerful spatial data modeling and analysis functions. This product allows the user to create, query, map, and analyze cell-based raster data, and to perform integrated vector-raster analysis.

APPENDIX D: INFORMATION SOURCES

Soil and Groundwater Standards for Petroleum Based Products

1. Many hazardous waste sites within DoD are petroleum-related spills. The Association for the Environmental Health of Soils (AEHS, Elmhurst, MA) annually conducts a survey of the soils and groundwater standards by various states. AEHS can be contacted at (413) 549-5170, fax (413) 549-0579.

2. Oliver *et al.* (1996) have provided a summary of the soil and groundwater standards for hydrocarbon contamination.

3. There is a Total Petroleum Hydrocarbon Criteria Working Group (TPHCWG), which has been working to standardize health risk based cleanup for petroleum contaminated soil and groundwater. In addition, there is a collaborative research program that has been organized and conducted under an agreement sponsored by the Petroleum Environmental Research Forum (PERF). This group includes the major petroleum producers, American Petroleum Institute, Gas Research Institute and the Air Force. The Gas Research Institute (1996) sponsored development of a workplan for environmentally acceptable endpoints for hydrocarbon-contaminated soils. The Air Force representative for the TPHCWG and PERF is Maj Wade Weisman of AL/OET, (937) 255-5150, Fax (937) 255-1474.

Cancer Potencies and RfD/RfCs

1. The Integrated Risk Information System (IRIS) is the preferred EPA source of toxicity information as the EPA's RfD or Carcinogen Risk Verification Endeavor (CRAVE) workshops have verified the data. However, IRIS is recognized to have many quality problems and incomplete references (NRC, 1994). Electronic access to IRIS is available via EPA subscription. The IRIS user support number is (513) 569-7254. This data set is incomplete and not all chemicals of concern will have IRIS information. See Template 4 for chemical of concern data sources.

2. The Health Effects Assessment Summary Tables (HEAST) are interim summaries with some verified RfDs and slope factors for specific chemicals. It normally contains a reference section for the current sources of toxicity information on which the RfDs and SFs are based. HEAST can be obtained by EPA subscription. HEAST data should be used only when IRIS data is not available.

3. When current information for specific chemicals is not available, the EPA National Center for Environmental Assessment (NCEA), formerly the Environmental Criteria and Assessment Office (ECAO) (513) 569-7300, will respond to contractors if they provide the name and address of their remedial program manager or regional risk assessment contact. They can provide general toxicological information and whether they have sufficient current information for specific chemicals on which to calculate RfDs and SFs.

4. Agency for Toxic Substance and Disease Registry (ATSDR) Toxicological Profiles have been prepared for over 275 substances. The profile includes general toxicological information and levels of exposure for lethality, cancer, genotoxicity, neurotoxicity, developmental and reproductive toxicity, immunotoxicity and systematic toxicity. Health effects are discussed by exposure route (oral, inhalation and dermal) and duration (acute, intermediate and chronic) for both animals and humans. Also, included are physiochemical properties, fate information, human exposure potential, analytical methods and summary of regulatory and advisory status. These profiles are available in print through NTIS (800) 336-4700; 119 profiles are available on CD-ROM with search capability through CRC Lewis Publishing (800) CRC-PRESS.

Websites

A global search for any topic such as human health risk assessment will yield information today that may not be available on the Internet tomorrow. Meanwhile new and other advanced information will emerge on the web. Appendices A through C provide website information on tools useful for human health risk assessment. As of January 30, 1997, interesting web sites were found pertaining to the general area of human health risk assessment:

1. The Health Risk Assessment Branch, AL/OEMH, at Brooks AFB, TX (http://www.brooks.af.mil/esoh/aloe4.htm) provided information on their services to DoD customers in regards to health based risk assessment. The last time the site was revised was February 27, 1996.

2. The Department of Energy (DOE) Environmental Management Directorate maintains a comparison of RCRA corrective action and CERCLA remedial action site at http://www.em.doe.gov/rcracerc/compar.html. This site was developed for DOE sites but should have some applicability to DoD sites. Naturally, any legal interpretation should be coordinated with the appropriate legal staff and risk managers (regulatory agencies). The site does discuss constituents of concern, standard analytical methods and OA/QC procedures for both RCRA/CERCLA sites. This site was last posted on May 11, 1995.

3. Dr. Paustenbach posted online readings for a course titled "Exposure and Risk Assessment" extracted from an article "Retrospective on U.S. Health Risk Assessment: How Others Can Benefit." The site is at http://aerosol.sph.edu/~liu/retrp/html. It provides an excellent overview of the history of risk assessment, the improving of the practice, alternative approaches and summary of risk assessment in other counties primarily the European community, Australia, and New Zealand. This site was modified on November 20, 1996.

4. The Presidential / Congressional Commission on Risk Assessment and Risk Management published a two volume report titled "Framework for Environmental Health Risk Management." This 1997 report and its precursor draft are available on the Internet at http://www.riskworld.com. The references for Volume I of the report contain a list of resources on risk assessment methodology and organizations which publish materials on various risk assessment technologies. It lists 18 organizations which are hotlines or clearinghouses.

5. Oak Ridge National Laboratory developed three reports on exposure assessment, ecological risk assessment and human health risk assessment which are being published as Armstrong Laboratory technical reports. These draft documents contain a wealth of information compiled

from the regulatory and peer reviewed literature. They are extensively referenced. Many data tables from other regulatory documents are presented and the reports make a useful consolidated reference.

APPENDIX E: HUMAN HEALTH RISK ASSESSMENT TEMPLATES

INTRODUCTION

The Human Health Risk Assessment Templates (HHRATs) will contain:

- New and/or updated risk assessment methodological guidance which is rapidly developing in the available literature,
- Risk assessment guidance as presented in the EPA's original Risk Assessment Guidance documents but impacted by several toxicological issues that have emerged, and
- Consistency in response to preparation of the Human Health Risk Assessment for any DoD need.

The HHRATs will provide the best available and most recent scientific and human health guidance available, and will describe the general technical approach used in the absence of any specific guidance on critical issues.

The HHRATs are organized into eight logical templates. Each describes several steps to be addressed and completed for effecting the human health risk assessment. The templates are summarized as follows:

- Template 1.0 (Requirements) describes the current requirements and a strategy for completing the risk assessment. The template also presents the sequence and interrelationships of sources, schedules, priorities, policies and stakeholders, and agreements that activate the risk assessment task process and support conduct of a risk assessment.

- Template 2.0 (Exposure Scenarios) discusses the geology, land use, contaminated media, the receptors and pathways of exposure. It includes interactions of physical, biological and chemical factors that are of concern and contribute to in assessing exposure conditions.

- Template 3.0 (Exposure Assessment) addresses background concentrations, chemical fate and transport, the distribution and occurrence of contaminant data among the media, and includes, chemical analysis, analytical data and their statistical treatment, data validation procedures, and assurance of data quality sufficient for conducting human risk. Fate and transport in various media and physical chemistry of the source materials are considered. Models used for media fate and transport will also be discussed.

- Template 4.0 (COC Data) discusses the published literature and sources of information available on which to draw information for the hazardous agent(s) in question. Biomedical and chemical indices and various databases and documents published by regulatory and health agencies will be considered as sources.

- Template 5.0 (Dose-Response Evaluation) describes the evaluation and analysis of the toxicological and health literature that will support the hazard and risk assessment initiative.

This template describes the adverse biological effects and critical target organ, the dose(s) eliciting that response, the pharmacokinetics, and dynamics of the chemical(s) in question, the quality of the data developed, and the potential association for extrapolation of animal data for use among humans.

- Template 6.0 (Risk Characterization) is a synthesis of toxicity information, the various physiological systems affected, and the estimate of risk from various media. The sufficiency of the experimental protocols, structure activity relationships, the difference of effects in various experimental animals and of high dose exposure to low dose extrapolation for humans and the current philosophies of interpretation of animal model data are critically analyzed. The use of physiological based pharmacokinetics (PB-PK), NOAELs and LOAELs are also considered. Also physiological default parameters will be examined together with the statistical and toxicological strategy or screening procedure that supported the selection of constituents of potential concern and of final concern (COPCs, COCs). It includes the carcinogenic risk as well as the non-carcinogenic risk and toxicity mechanisms and philosophies. The value of human clinical and epidemiological information, animal models and experimental toxicological data are critically analyzed.

- Template 7.0 (Data Gaps) discusses the use of available data and/or the lack of data considered necessary for developing a realistic and functional hazard or risk assessment. Individual gaps affecting the risk analysis are identified for future research.

- Template 8.0 (Uncertainty Assessment) describes the necessity of an uncertainty analysis. This template is judgmental , in that it describes the assessor's confidence level in the risk characterization. Current efforts by risk scientists have suggested methods for quantifying uncertainty associated with risk analysis. These methodologies will be provided where it is possible in order to increase our understanding of the risk characterization.

TEMPLATE 1: REQUIREMENTS

Background

Each Human Health Risk Assessment (HHRA) is conditioned by the social, political, physical and legal limitations that have evolved over time. Particularly when the DoD is proposing to invest resources into clarifying a risk area there must be a strong relationship to the Service's basic interest areas to justify the effort. Health effects science and technology must be targeted to meeting the priorities of their sponsors and customers. It is important to set the context for which a HHRA is being performed to increase the likelihood of a satisfactory assessment.

Objective

An agent of concern must be proposed, exist or have existed at a DoD facility to compete for resources in a HHRA. Additionally, someone must be concerned over its potential health outcomes and be willing to be designated as a sponsor or customer. This individual isn't necessarily a funding source, but could be. Requirements may have been already formally identified by a customer; they may be in the formative stages or they may exist but be

unidentified. Several agencies have created databases of lessons learned and past experience at various hazardous waste sites. Likewise, each of the agencies have active processes on-going to list and characterize evolving requirements. Opportunities to apply the generic HHRA process can occur during the science and technology communities search to fill data gaps, during preliminary risk assessment, during negotiation of site specific clean-up criteria, during regulatory review, during risk communication or during planning of on-going remediation efforts. There can be both agent or site specific applications.

Assumptions

Government managers have the principal responsibility to determine their resource allocation plan for the future. Technical services to extract, analyze and refine the requirements and put them into a consistent format is a valid task for contractor performance.

Template

1.0 Requirements Identification

1.1 Characterize the potential requirement through an interview with any identified risk manager. Refine the characterization to identify current uncertainties in terms of the risk assessment paradigm including characteristics of the stressors and receptors involved.

1.2 Assess the status of existing formalized requirements addressing the issue by reviewing the status of requirements data bases. These include the Human Systems Center's Technology Planning Integrated Process Team (TPIPT) Technology Needs System, Defense Environmental Information Exchange (DENIX), AFCEE's Installation Restoration Program Information Management System (IRPIMS) database, Corps of Engineers database, ATSDR's HAZDAT database, Internet databases for Department of Energy, Department of Transportation, Fish and Wildlife Service, National Oceanic and Atmospheric Administration, and state and industry databases.

1.3 Draft a position paper which describes the understanding of the evolving requirement and coordinate the position paper with the risk manager.

2.0 Assess Priority

2.1 Determine whether the evolving requirement involves a site listed as a National Priority List location; if so, determine the site score. The EPA provides information on their Hazard Ranking System on the Internet at "http://www.epa.gov/superfund/oerr/products/prescore".

2.2 Assess whether ATSDR has identified the stressor(s) with their ranking of compounds with public health concerns and any existing score.

2.3 If the evolving requirement involves military installations, determine the priority with respect to mission impairment, pervasiveness, hazard severity, regulatory risk, cost of not resolving the

requirement, goals, political sensitivity, uniqueness to the military, schedule demands, affordability, technological availability and impact to highly valued resources.

2.4 Identify any on-going efforts to resolve the requirement, potential for success, and innovation approaches not in progress.

2.5 Although risk-based resource allocation priority systems have not been generally successful, there are methodologies presented which can provide relative risk insight. These systems generally fail when the risks faced by specific stakeholders are ranked low compared to other sites. Information on ranking systems can be obtained on the Internet at the following sources and others:

2.5.1 "http://www.em.doe.gov/irm"
2.5.2 "http://atsdr.gov:8080/atsdrhome"
2.5.3 "http://calepa.cahwnet.gov/oehha/docs/raac/final

3.0 Program for Resources

3.1 Generate a rough order of magnitude estimate for labor, materials, travel, schedule and deliverables using projects of similar type or by bottom-up engineering estimates. Consider the potential for inflation should the project not start immediately.

3.2 Coordinate with the risk manager to identify the source of any existing program resources which can be allocated to the requirement.

3.3 Support the risk manager in submitting budget requests to appropriate funding sources including submissions of A106 requests for future year budgets.

3.4 Identify limitations and constraints in meeting the requirement including technology availability, schedule conflicts, policy constraints and special concerns. Insure any site specific records of decision or other agreements are reviewed and understood.

4.0 Secure Direction

4.1 Research requirements of similar nature to identify stakeholders, current policy, potential proponents and detractors.

4.2 Advocate resolution of the evolving requirement with stakeholders, obtain their involvement in the solution process.

4.3 Secure formalized direction to proceed.

5.0 Develop an Implementation Plan

5.1 Formalize both the technical and management approach into an implementation plan which includes a master schedule. Allocate elements of the requirement to deliverables following a work breakdown structure.

5.2 Convert the implementation plan into an acquisition strategy including a project specific approach for performance.

TEMPLATE 2: EXPOSURE SCENARIOS

Background

The environmental site can range from a workplace, manufacturing facility, Superfund site, hazardous waste site governed by the Resource Conservation and Recovery Act (RCRA), a spill site, and so on. This exposure scenario template is the method that can be used to evaluate exposure setting with the goal to develop risk-based clean-up criteria for a site. Recently the term "conceptual model" has been used to describe the output of the problem definition step. The Presidential / Congressional Commission on Risk Analysis and Risk Management report (http://www.riskworld.com) emphasizes this step in their risk management framework.

Objective

Exposure scenario development is performed with the expressed intent of gathering contaminant site characterization, receptor identification, transport mechanism identification, completed exposure pathway identification and additional monitoring requirements identification. The information gathered during this protocol will be used to assess exposures and complete a HHRA for contaminants of concern at a specific environmental site or within a specific use of the hazardous material.

Assumptions

Exposure scenario developments completed according to this protocol are tailorable and iterative. The exposure scenario will be tailored and closure criteria will be provided by two types of customers: Toxicology Principal Investigators (PI) and Environmental Site Risk Managers. This template is written to address the typical case in HHRA literature searches. The exposure scenario or conceptual model should be coordinated with the customer and especially the risk managers to assure that there is concurrence and agreement on the next step: how to proceed with exposure assessment. Initial scenarios should be broadly defined to assure potential pathways are not prematurely dismissed.

Template

1.0 Identify Contaminant Sources

1.1 Identify primary sources of contamination.

1.1.1 Find the site name, location, product storage, piping/distribution, operations, waste management practices. Describe the primary contaminant source.

1.1.2 Describe what the primary contaminants are with early monitoring data and historical review. Assure adjacent regions are assessed for related sources and credible background locations.

1.2 Identify secondary sources of contamination.

1.2.1 Find the impacted surficial soils (less than two feet depth and less than six inches).

1.2.2 Find the impacted sub-surficial soils (greater than two feet depth).

1.2.3 Describe the dissolved groundwater plume.

1.2.4 Describe the free-phase liquid plume.

1.2.5 Describe impacted surficial soils, sediments, or surface water.

2.0 Identify Transport Mechanisms

2.1 Gather Site Characterization Information.

2.1.1 Characterize exposure setting by evaluating the geographical, climatological, geological, surface topographical and hydrogeological information existing for the site.

2.1.2 Gather appropriate site parameters as related to the exposure setting. Most of these parameters can be gathered from the site characterization documentation.

2.1.2.1 For climatology: wind, temperatures, rainfall, etc.

2.1.2.2 For geology: land type, land use, etc.

2.1.2.3 For surface topography: historical and current runoff paths, wind erosion etc.

2.1.2.4 For hydrogeolography: aquifer type, drinking water location, speed of groundwater movement etc.

2.2 Identify potential transport from the site characterization.

2.2.1 Research data already collected for:

2.2.2.1 Could wind erosion and atmospheric dispersion transport the contaminants?

2.2.2.2 Could volatilization and atmospheric dispersion transport the contaminants?

2.2.2.3 Could leaching and groundwater transport move the contaminants?

2.2.2.4 Could mobile free-liquid migrate the contaminants?

2.2.2.5 Could stormwater/surface water transport the contaminants?

2.2.2 If yes to any of the questions in 2.2.2.1 to 2.2.2.5, than must conclude a potential exposure pathway exists.

3.0 Identify Existing Pathways of Exposure

3.1 Potential pathways include:

3.1.1 Soil ingestion/dermal absorption.
3.1.2 Particulate and/or gaseous soil inhalation.
3.1.3 Potable water ingestion/inhalation/dermal absorption/food chain uses.
3.1.4 Recreational use/sensitive habitats.

4.0 Identify Potential Receptors

4.1 Characterize receptors by residential, commercial/industrial, construction worker, sensitive habitat, and other for all existing pathways.

4.2 Describe corrective contingencies for those emergency situations.

5.0 Determine Further Monitoring Requirements

5.1 Create monitoring protocols for those existing exposure pathways where a receptor exists and concentrations of contaminants do not exist.

5.2 Check monitoring protocol for detection levels to insure that data collected will be appropriate to evaluate risk to the receptors.

5.3 Complete health based monitoring.

TEMPLATE 3: EXPOSURE ASSESSMENT

Background

This exposure assessment template is the method that can be used to evaluate exposure doses and routes with the goal to develop risk-based clean-up criteria for a site.

Objective

Exposure dose development is performed with the expressed intent of gathering confident exposure data, confident background level evaluation for contaminants identified at the site, chemical fate and transport, the distribution and occurrence of contaminant data among the media, and the chemical analysis, analytical data validation and quality assurance. The information gathered during this protocol will be used to assess exposures and complete a

HHRA for contaminants of concern at a specific environmental site or specific use of the hazardous material.

Assumptions

Exposure assessment development completed according to this protocol are tailorable and iterative. The exposure will be tailored and closure criteria will be provided by two types of customers: Toxicology Principal Investigators (PI) and Environmental Site Risk Managers. The construction of this exposure assessment template assumes that the previous templates gathered the appropriate contaminant and basic site characterization monitoring for the site (i.e. monitoring has been completed for air, water or soil and a hazard exists) and that additional monitoring as required by the exposure scenario template has been completed and data are available for interpretation and analysis. This template also assumes that the exposure pathways, contaminant sources and receptor populations have been identified. This template is written in accordance with the American Society for Testing and Materials (ASTM) Standard E 1739-95, "Standard Guide for Risk-Based Corrective Action at Petroleum Release Sties", the EPA Exposure Factors Handbook and the Oak Ridge National Laboratories "Review of Exposure Assessment Guidelines". Many sites for which a HHRA will be performed will have a sampling and analysis plan. That plan should contain the relevant assumptions for treating "hot spots" and background levels.

Template

1.0 Determine Background/Naturally Occurring Concentrations for Each Media

1.1 Gather all background/naturally occurring concentrations for each media that has a completed exposure pathway and receptor population. Commonly occurring levels of each contaminant must be considered in risk assessment. The background levels of contamination (naturally occurring levels) must be monitored and statistically validated. These values are usually necessary for heavy metals contamination.

1.2 Complete statistical analysis of the background/naturally occurring contaminant concentrations to gain a 95% confident limit.

1.3 Levels of Chemicals of Potential Concern (COPC) which fail to be detected above the method detection level in a sample or found in the background must have a defined protocol for treatment. The sampling plan should establish assumptions. The sampling plan should also define the treatment of hot spots. Failure to achieve stakeholder concurrence can lead to discord when artificially high levels induced by assumptions on treatment of detection levels influence the calculated risks.

2.0 Complete Statistical Analysis of the Data

2.1 Complete the 95th percent upper confidence limit (UCL) on the arithmetic mean concentration.

2.2 The U.S. EPA Exposure Assessment Guidelines (1992a) state that using a frequency distribution in a statistical analysis such as a Monte Carlo simulation would reduce the uncertainty in characterizing the distribution of exposure and risk across the entire exposed population. The ASTM Standard supports this method as well.

2.3 Use the most certain contaminant concentration in an environmental medium to estimate exposures by 2.1 or 2.2. Scrutinize all data for validity according to laboratory analysis and method detection limits/practical quantitation limits.

3.0 Compare the Contaminant Concentrations to Background/Naturally Occurring Concentrations

3.1 If contaminant concentrations exceed the background/naturally occurring concentrations, than an exposure assessment should be completed in accordance with the HHRA. The contaminants that do exceed background are the Contaminants of Potential Concern (COPCs).

3.2 If contaminant concentrations do not exceed the background/naturally occurring concentrations, consult the local regulatory agencies on corrective action guidance.

4.0 Describe Potential Fate and Transport of Contamination

4.1 Using models (See Appendix A), describe the potential impact of the contamination due to fate and transport.

4.2 Evaluate all potential future contamination.

5.0 Describe Contaminant Distribution and Occurrence

5.1 If data available is not confident (less than 95% confidence), than the distribution of the contaminants can be described through models. Potential levels occurring at varying points and times can be predicted.

5.2 If the contaminant concentrations are potentially naturally attenuative than risk based doses must be calculated.

5.3 The contaminant distribution and occurrence may create further COPCs which need monitoring so that a health risk assessment can be performed. At times, chemicals will combine in aquifer/dispersion settings and create future potential hazards which were not thought to be there.

6.0 Evaluate Contaminant Concentrations Against a Risk Based Screening Tool

6.1 Determine Risk Based Screening Levels for all Contaminants with respect to their potential route of exposure.

6.2 Compare Concentrations to the Risk Based Screening Tool Concentrations.

6.2.1 Do the chemical concentrations at our site exceed the Risk Based Screening Levels?

6.2.2 If yes, is remediation to the Risk Based Screening Levels practical? Check background concentrations.

6.2.2.1 If yes, Complete a remedial action program.

6.2.2.2 If no, Go to 6.2.3.

6.2.3 If no, is remedial action appropriate?

6.2.3.1 If yes, Complete a remedial action program.

6.2.3.2 If no, Complete further monitoring or calculate an exposure dose.

7.0 Calculate an Exposure Dose

7.1 For each completed exposure pathway, media and receptor population determine the intake/exposure dose by the equations in the EPA Risk Assessment Guidelines (1989a).

7.2 Determine the following exposure parameters/factors in addition to the concentration for each exposure route/media to be used in calculating a dose.

7.2.1 For drinking water: Ingestion rate, Exposure frequency, Exposure duration, Bodyweight of exposed population, Averaging time (365 days/yr. for noncarcinogens, 70 yr. for carcinogens).

7.2.2 For Dermal Doses: diet fraction, lifetime, permeability coefficient, Average surface area exposed, averaging time, bodyweight, and exposure duration.

7.2.3 For ingestion and inhalation: Exposure duration, intake rate, averaging time, bodyweight, absorption fraction and average daily dose.

7.2.4 For other dose determinations consult the EPA RAGS Human Health Evaluation Manual (1989a), Risk-Based Corrective Action (ASTM, 1995) or the Oak Ridge National Laboratories "Review of Exposure Assessment Guidelines" (1995).

8.0 Determine Further Monitoring Requirements

8.1 Where data is not statistically confident for a potential exposure pathway and receptor, future monitoring must be completed.

8.2 Where new COPCs have been identified due to distribution, fate and transport, new monitoring must be completed.

8.3 Where exposure concentrations were calculated based on data which was inaccurate due to the method detection limits or equipment practical quantitation limits being too high/low etc., further monitoring must be completed.

9.0 Complete Remedial Action Program as Required

9.1 Survey all guidance for necessary parameters.

9.2 Research other fate and transport models.

9.3 List References.

9.4 Research any distribution and occurrence models.

9.5 Describe modeling limitations.

9.6 Describe Data Quality Objectives (DQOs) and how they should be set in accordance with risk assessment.

9.7 Determine the point at which background is similar to contaminant concentration.

TEMPLATE 4: COC DATA

Background

The first step to deriving health based clean-up criteria is to ensure that the toxicity information available for each COC at a site is researched, developed (when not available) and then applied appropriately. This template is the method that can be used to gather already existing information on the properties and toxicity of a COC.

Objective

This template outlines the procedures necessary to conduct a toxicological literature search typically performed. Literature searches are performed with the expressed intent of gathering toxicological information about specific contaminants of concern as quickly and completely as possible. The toxicological information gathered during literature searches will be used to assess toxicity, identify future toxicological studies to fill data gaps or conduct HHRA for contaminants of concern at a specific environmental site or within a specific use scenario. Additionally, the toxicological information gathered will help to confirm human and ecological health based clean-up criteria which presently exist or aide in the development of the clean-up criteria where none exist. Other data gathered during the literature search such as physical properties and environmental fate and transport mechanisms will be utilized in the exposure quantification.

Assumptions

Literature searches completed according to this template are tailorable and iterative. The literature searches will be tailored and closure criteria will be provided by customers: Armstrong Laboratories Toxicology Principal Investigators and Environmental Site Risk

Managers. The construction of this literature search template assumes that the previous templates defined appropriate COCs. This template is written to address the typical case in HHRA literature searches.

Template

1.0 Research COCs

1.1 Obtain a complete listing of all COCs and their Chemical Abstract Service (CAS) registry numbers.

1.1.1 Listing is generated by the Principal Investigator (PI), site risk manager or completed HHRA template. List may also include metabolites of the COCs.

1.1.1.1 An interview is necessary with the toxicology PI or site risk manager to obtain previously collected data for the COCs.

1.1.1.2 Data which may have been collected includes: CAS numbers, Material Safety Data Sheets (MSDSs), metabolites and synonyms.

1.1.1.3 Assess processes historically present at the site and surrounding area to aid in identifying co-contaminants potentially present.

1.1.2 The customer (PI or risk manager) must work closely with information science searchers to provide guidance on the literature needed for the COCs.

1.2 Gather information on the chemical identity and physical/chemical properties of each COC (consider compounds and known contaminants).

1.2.1 Obtain summary chemical information on the COCs. The ATSDR Toxicological Profiles, ATSDR Public Health Statements, Chemical Data Bank Compact Disk (ChemBank) and TOMES + are the best sources. ChemBank contains the following databases: National Institute of Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS), EPA's Oil and Hazardous Materials Technical Assistance Data System (OHMTADS), National Library of Medicine's Hazardous Substance Data Bank (HSDB), U.S. Department of Transportation's (DOT's) Chemical Hazards Response Information System (CHRIS). The TOMES + database contains the following databases: RTECS, CHRIS, NIOSH Pocket Guide to Chemical Hazards. Other sources of summary chemical information are: Hazardous Waste Remedial Action Program (HAZWRAP), a support effort to DOE and the Risk Assessment Handbook.

1.2.1.1 Obtain chemical identity information: Chemical name, Trade name, synonyms, chemical structure, chemical formula, CAS Number. Best Source: ATSDR Toxicological Profiles or TOMES + or ChemBank: HSDB or RTECS.

1.2.1.2 Obtain Physical and Chemical Properties: Molecular Weight, Color, Physical State, Melting Point, Boiling Point, Density at 20°C, Odor, Solubility, Partition Coefficients [Octanol-Water or K_{ow}, K_{oc}], Vapor Pressure at 20°C, Henry's Law Constant), Autoignition Temperature, Flashpoint, Flammability Limits in Air and any Conversion Factors from air to water). Best Source: ATSDR Toxicological Profiles or TOMES + or ChemBank: HSDB, CHRIS, OHMTADS.

1.2.2 Gather basic fate and transport data for the contaminants of concern: including naturally occurring sources and typical background levels of the contaminant. Best Source: ATSDR Toxicological Profiles or TOMES + or ChemBank: HSDB.

1.3 Gather basic toxicity information.

1.3.1 Obtain basic pharmacology data. Such as typical therapeutic uses or drug warnings. Metabolites may also be reported. Best Source: ChemBank: HSDB (Pharmacology Section).

1.3.2 Gather summary toxicity information. Best Source: ATSDR Toxicological Profiles, and ATSDR Public Health Statements. If these documents have not been published for the COC, consult the ChemBank or TOMES +: RTECS or HSDB.

1.3.2.1 The ATSDR Toxicological Profiles typically summarize the data available for levels of significant exposure by inhalation, oral and dermal/ocular exposures. The health effects discussed are categorized by acute, intermediate and chronic exposures: death, systemic, immunological, neurological, developmental, reproductive, genotoxic effects and cancer. No Observed Adverse Effect Levels (NOAELs), Lowest Observed Adverse Effect Levels (LOAELs), uptake, bioavailability, distribution, toxicokinetic and biomarker information should be obtained in the Toxicological Profiles as well.

1.3.2.2 The ATSDR Public Health Statement (first few pages of the Toxicological Profiles) will provide basic information on the common occurrences/uses of the material, common effects from the material and how to medically monitor in case of an exposure.

1.3.3 Gather Occupational Health data. The American Conference of Governmental Industrial Hygienists (ACGIH) occupational health exposure limits guidebook (1993) summarizes the International Agency for Research on Cancer (IARC) categories assigned, the NIOSH Recommended Exposure Limits (RELs), Canadian, Netherlands, Swedish, Russian, British Standards, Short Term Exposure Limits (STELs) based on a 15 minute exposure and the Ceiling Limits based on a one-time, peak exposure.

1.3.4 Gather information on acute and chronic exposure risk levels from the Integrated Risk Information System (IRIS) and Health Effects Assessment Summary Tables (HEAST) databases. These values are based upon route of exposure and may not exist for the contaminant you are evaluating.

1.3.4.1 Obtain the current noncancer reference doses for each exposure route (RfD, RfC).

1.3.4.2 Obtain the cancer slope factors.

1.3.4.3 Identify non-classical toxicological endpoints, such as reproductive effects, developmental effects, or endocrine disruption effects.

2.0 Evaluate Data

2.1 Review all available summary physical, chemical and toxicological data. Apply to customer's exposure scenarios.

2.2 Work with the customer to insure data is complete.

2.3 If more data is needed, determine keywords for further, more detailed literature searches using Medline, Toxline or other available databases.

3.0 Gather Toxicology Literature

3.1 Gather abstracts relating to COC. Some sources include Silver Platter Information Retrieval System on Window (WinSPIRS), Medline and Toxline. Abstracts must then be reviewed and articles selected for retrieval.

3.1.1 To searching for abstracts via WinSPIRS, use the following guidance.

3.1.1.1 Search for Chemical Name or Names.

3.1.1.2 Include CAS number.

3.1.1.3 Use Boolean terms -and, or, not, in (searchable fields only). Can use wildcard symbol (*).

3.1.1.4 Search chemical name or CAS number and keywords relative to the search (e.g., human, biological monitoring, blood, urine, pharmacokinetic, etc.) depending upon needed information. Remember: target organ/tissue, route of exposure, noted authors in the field, selected years, species, chemical class, synonyms, abbreviations, occupational or occupat* and study type.

3.2 Gather published literature from selection of abstracts. For the Wright-Patterson AFB area, the best sources are: Tri-Service Toxicology Library, Wright-Patterson Medical Center Library, Wright State Fordham Health Sciences Library, University of Dayton Roesch Library and University of Cincinnati Environmental Health Sciences Library, Wright State Dunbar Library, Wright Laboratory Science and Technology Information Library and the University of Cincinnati Health Sciences Library.

3.3 This process is iterative. Therefore, at any point along this template, it may be required that we start at the beginning and repeat the process for another COC. Additionally, once the literature is gathered, the literature must be reviewed for older, valuable sources of information. This process is never really complete. However, closure occurs once the exit criteria established by the customer has been met.

4.0 Follow on Actions

4.1 Develop a resource listing of home pages etc. from all databases or libraries used in searching (See Appendix D for some web site information).

4.2 Check to be sure that literature search gathers all parameters needed for RBCA, Risk Assessment and Health Risk Assessments.

4.3 Create a timeline for when all parameters or literature search data is needed within the HHRA process.

TEMPLATE 5: DOSE RESPONSE EVALUATION

Background

The purpose of the toxicological analysis is to evaluate biologically pertinent data, to determine whether the exposure to any agent poses a hazard to humans and under what conditions the hazard may express itself. The process of biological information analysis assesses data from human experience and animal models. The peer reviewed information as published in refereed journals is evaluated according to the current science and philosophies to construct a total understanding of all the biological effects of any given agent. COC's target organ or tissue, its mode of action, the dose response relationship and the implications for human hazard are of paramount significance, since the strength of the combined analysis provides the support for decision making and reliability of any conclusions. Accordingly, the following philosophy will be used when considering biomedical data:.

a) Clinical human data, when available, is given first priority,
b) Epidemiological data, properly qualified, is considered next, and
c) Experimental animal toxicity data and cellular data are assessed and used as supportive toxicity evidence.

Template

1.0 Dose Response Evaluation

1.1 Dose response evaluation is the fundamental relationship that describes the response in a biological organism, with an applied dose. The data derived from such studies are fundamental and used for identifying toxicity values, described as a No Observed Adverse Effect Level (NOAEL), the Lowest Observed Adverse Effect Level (LOAEL) and the No Observed Effect Level (NOEL), and carcinogenic relationship. The dose response data is presented, usually as a curve form, and can be linear, concave or convex or bimodal. It describes the distribution of some effect within a population or the degree of change, as a function of changing exposure concentration. These values are currently recommended to be used in concert with the PB-PK and possibly, benchmark doses, as valuable adjuncts that may assist in extrapolation of animal data when preparing the risk estimate. The use of animal data or human data, differing dose values, acute instead of chronic data, judgments of uncertainty, and confounding variables introduce as much as 10 fold as safety factors. The amount, and/or the robust nature of the data dictates the value of the study. Therefore extrapolating potentially safe doses for humans from experimental data, interpretation of experimentally derived toxic effects must be supported by:

1.1.1 Consistency among responses from animal data,
1.1.2 Temporally appropriately relations of dose, duration and toxic response,
1.1.3 Biological gradients relating increased responses to higher dose
1.1.4 Specificity of response, given a unique exposure, and
1.1.5 Biological coherence of what is known about the biology of the toxic response or the disease and its natural history.

2.0 Sex, Age, Animal strain, Length of Study, Route of Exposure

2.1 Each of these variables can alter the biological (toxic) response of any animal and provide differences in end point response. Biological responses may be similar, such as additive or synergistic or dissimilar, such as antagonistic. The resulting effects are not easily understood. Such data is difficult to interpret unless there is a standard reference document to provide agreement in interpretations.

3.0 Pharmacokinetics

3.1 PB-PK analysis is physiologically based pharmacokinetics analysis. PB-PK assists in understanding the agents mode of action and activity, and estimates the amount of a toxic agent or its metabolite that will reach the target tissue, rather than the dose estimated from ambient exposure to environmental media. It has limitations to the species modeled but finds increased use as an acceptable, and valuable, tool in risk analysis. It should be discussed and presented if appropriate.

4.0 Metabolism

4.1 Metabolism is a four step process (Absorption, Distribution, Metabolism, and Excretion) depicting the biological activity of an agent. It describes biologically effective doses, absorption paths, local or systemic toxicity, transport and distribution of the agent, the target organ, effects of the cell on the chemical and of the chemical on the cells biochemical functions, the fate of the parent compound and conversion to other metabolites and excretion rates.

5.0 Extrapolation

5.1 The use of short term vs. longer term toxicity tests and the various animals and if they are appropriate to the desired or expected end point must be determined. This is especially critical for those effects on organs peculiar to the lab animal without counterpart in humans. Assessment of the critical journal reference study and appropriateness of the experimental procedure to the end point or results should be conducted by qualified toxicologists.

6.0 Interpretation of Carcinogen Studies

6.1 Interpretation of Carcinogen Studies should include:

6.1.1 a description of the qualifying factors that denote carcinogenicity,
6.1.2 a discussion of the pathological data developed from long term studies,
6.1.3 a description of the use and limitations of the animal models used,
6.1.4 an assessment of the dose and exposure conditions,
6.1.5 evaluation of the mathematical models used to describe the low dose relationships of carcinogens such as one-hit, multihit, Weibull or multistage,
6.1.6 an analysis of the pathobiological consistency of the tissue response.

6.1.7 examination of the genotoxicity studies for carcinogenicity and also examination of their potential to transmit heritable mutations.

7.0 Epidemiology Studies

7.1 Epidemiology studies describe the occurrence and the distribution of diseases or some adverse effects among an exposed population. Despite their limitations, these studies can be informative since they reflect direct observation effects in humans. Limitations that can occur and should be examined include;

7.1.1 Bias of the study.
7.1.2 Type of study used (retrospective, prospective).
7.1.3 The possibility of confounding factors.
7.1.4 Inadequate quantification of exposures.

8.0 Radiological Assessments

8.1 Radiological assessments will be included when appropriate using the EPA and DOE data for exposure, shielding, and absorption.

TEMPLATE 6: RISK CHARACTERIZATION

Background

The risk characterization is an interactive process that conveys the hazard identification, dose-response, and exposure assessment information in a meaningful way to the risk managers. It will include quantitative estimates of the cancer and noncancer hazards and an overall evaluation of the quality of the information in the risk assessment analysis. The National Research Council (NRC, 1996) proposed five key objectives for risk assessments: (a) Getting the science right, (b) Getting the right science, (c) Getting the right participation, (d) Getting the participation right, and (e) Developing an accurate and balanced summary. It recognized multiple levels of rigor for risk assessments for routine and complex issues. The importance of value judgments about what is important and relevant for those complex issues was recognized to facilitate more widely understood and accepted decisions.

Objective

Risk characterization, as the final step of the risk assessment, is to serve as a bridge with the risk management process. In this process, decisions are made on the basis of the public health impact as determined by the risk characterization and the criteria specified in the appropriate statute (i.e., RCRA or CERCLA).

Assumptions

The current practice of the theoretical increase in cancer risk at one in one million or even one in 10,000 from exposure to an environmental contaminant should not be depicted as a serious health risk. Risks have been presented as the upper, not the best, estimate of risk. This practice is done to assure less likelihood of underestimating the risk. The actual risk could, in fact, be zero. It is critical to convey to the reader that although these conservative practices are likely to overestimate the risk, situations where the risk may be underestimated can exist. If this is believed to be the case, this should be clearly stated in the risk characterization section. The four elements to a risk characterization are the generation of the risk estimate, qualitative uncertainty description (see the uncertainty template for discussion), risk estimate presentation and risk analysis results communication.

Template

1.0 Quantitative Risk Estimate

1.1 Generation of the quantitative risk estimate includes:

1.1.1 Exposure assessment information is combined with the dose response information. This is a different process for noncarcinogens and carcinogens.

1.1.1.1 Noncarcinogens - the dose estimate (E) for each COC is divided by the Reference Dose (RfD) to obtain the hazard index (HI). The HIs for multiple routes or compounds of similar toxic action can be summed. If the HI is less than one, it is unlikely that the chemical exposure(s) will cause adverse health effects. If HI is greater than one, adverse health effects are more likely and remedial actions should be considered.

1.1.1.2 Carcinogens - the chronic daily intake (CDI) averaged over 70 years is multiplied by the slope factor to yield an upper bound on the probability that lifetime exposure to this COC at the CDI will lead to excess cancer risk.

2.0 Non-Cancer Studies

2.1 Among non-cancer studies, developmental, endocrine, reproductive, neurological and behavioral responses should be assessed and discussed separately since such data may suggest the possibility of reproducible or heritable toxic effects that occur in children or unborn fetuses. A loss of psychological integrity may occur, although overt toxicity is absent.

3.0 Individual Risk

3.1 For individual risk, the following questions should be answered (EPA Guidelines for Exposure Assessment, 1992a):

3.1.1 Are individuals at risk from exposure to the substances under study?

3.1.2 To what risk levels are the persons at highest risk subjected? Who are these people, what do they do or where do they live to put them at this higher risk?

3.1.3 Can people of higher susceptibility be identified?

3.1.4 What is the average individual risk?

4.0 Population Risk

4.1 For population at risk, the following should be addressed (EPA Guidelines for Exposure Assessment, 1992a):

4.1.1 How many cases of a specific health effect can be probalististically forecasted for a population of interest over a specified time period?

4.1.2 For non-carcinogens, what fractions of the population exceed the Reference Dose (RfD), reference concentration (RfC) or other toxicity benchmark?

4.1.3 For carcinogens, what fraction of the population exceed a specified risk level or series of risk levels (such as $1X\ 10^{-6}$, $1X10^{-5}$, $1X10^{-4}$).

4.1.4 Are there any specific subpopulations groups at higher exposure, dose, or risk?

5.0 Risk Estimate Presentation

5.1 Risk estimate presentation will depend on the legal mandates that apply but normally a table listing the estimated risk for the exposed population by the route of exposure is included. Per the EPA Guidelines for Exposure Assessment, 1992a, the presentation should include:

5.1.1 A qualitative weight of evidence conclusions concerning the likelihood that a chemical may pose serious hazards to human health, the nature and severity of the observed effects and by what routes these effects are seen to occur.

5.1.2 For noncancer effects - the does-response behavior of actual effects as well as the shape and slope of the dose-response curves for the toxic end points should be discussed. How was this information used to determine the dose-response assessment?

5.1.3 Are estimates of the exposure magnitude, route, duration and pattern of exposure, relevant pharmacokinetics, number and characteristics of the exposed population compatible with the hazard identification and dose-response assessments?

5.1.4 The numerical estimates should be accompanied with descriptive information conveying uncertainty in an objective and balanced manner (See Uncertainty template).

5.1.5 Does the risk characterization include ranges of the exposure derived from exposure scenarios as well as multiple risk descriptors (central tendency, high end individual risk, population risk, important subgroups (if known)?

6.0 Risk Communications

6.1 Risk assessor and risk manager - The risk assessor provides individual and population risk estimates (normally point estimates with ranges) and qualitative description of the uncertainties.

6.2 Risk manager and public - Normally the risk manager provides the point estimates with ranges without uncertainties discussion.

TEMPLATE 7: DATA GAPS

Background

Upon completion of the analysis, the degree of confidence one has in the data is reflected by the data gaps analysis. Any inability to adequately characterize risk, frequently is due to the lack of human data and/or experimental animal model research data. These items will be identified during the hazard and dose response evaluation and analysis and research studies will be proposed to fill these information gaps.

Template

1.0 Data Gap Analysis Results

1.1 The results of data gap analysis will be to identify the data that are missing or unavailable, the impact on risk or in understanding toxicity, and presentation of a research protocol design that will provide the missing information. Among possible targets for additional research are;

1.1.1 Additional environmental media exposure data,
1.1.2 Reproducible dose response and/or metabolic data,
1.1.3 Use of specific non-primate animal models,
1.1.4 Confirmation of critical target organ/tissues responses,
1.1.5 Consistency of response among animal models,
1.1.6 Ultra-structural/histological data that demonstrates biological consistency,
1.1.7 Short term genetic and DNA chromosomal tests,
1.1.8 Structure activity relationships,
1.1.9 Specific physiological system studies that meet a specific objective.

2.0 Additional Critical Analysis

2.1 Studies most frequently targeted for further additional critical analysis are;

2.1.1 Sub-chronic and chronic toxicity,
2.1.2 Pharmacokinetic/dynamic,
2.1.3 Local/systemic inhalation or dermal toxicity,
2.1.4 DNA, mutagenic, genotoxic cellular changes,
2.1.5 Developmental, feto/maternal toxicity, reproductive, endocrine, and,
2.1.6 Immunological and neurological data,
2.1.7 Human epidemiological studies are frequently recommended to characterize known occupational or public health exposures and human responses.

TEMPLATE 8: UNCERTAINTY ASSESSMENT

Background

Uncertainty analysis will involve each step of the risk assessment (hazard identification, dose-response assessment, exposure assessment, and risk characterization). As the uncertainty analysis affects the eventual risk estimate, it is normally considered a part of the risk characterization step. EPA recognized the importance of fully specifying the assumptions and uncertainties inherent in risk assessments to place risk estimation in the proper perspective (EPA, 1989a).

Objective

Provide issues that should be considered in a qualitative discussion of uncertainties. The following template will provide the issues by risk assessment step (NRC, 1994).

Template

1.0 Hazard Identification

1.1 What is known about the agent's capacity to cause cancer or other adverse effect in human or in lab animals?

1.1.1 What is the nature, reliability and consistency of the studies in human and in lab animals?

1.1.2 Is there any available information on the mechanistic basis for activity?

1.1.3 What is the relevance of the lab animal response to the human outcome?

1.1.4 What is the range of credible toxicity values?

2.0 Dose Response Assessment

2.1 What is known about the biological mechanisms and dose-response mechanisms and dose-response relationships underlying any observed effects in lab or epidemiological studies?

2.1.1 Is there a relationship between the selected extrapolation model and the available information on biological mechanism?

2.1.2 Were the appropriate data sets selected from the range of possible potencies in lab animals and humans?

2.1.3 Is the basis for selecting interspecies dose scale factors from lab animal to human appropriate?

2.1.4 Are the exposure routes use in lab animal studies the same as the expected exposure routes? If not, has the potential effects of the different exposure routes been addressed?

2.1.5 Other uncertainties analyses factors described in the EPA RAGS (1989a) include:

2.1.5.1 Is there a potential with multiple COC exposures for synergistic or antagonistic interactions?

2.1.5.2 If appropriate, is there discussion on calculating lifetime cancer risk on the basis of less than-lifetime exposures?

2.1.5.3 Part A to the EPA RAGS (EPA, 1989a) discusses approaches to adjust exposure levels for absorbed verses exposed dose.

3.0 Exposure Assessment

3.1 What is known about the paths, patterns, and magnitudes of human exposure and number of people likely to be exposed (EPA, 1990)?

3.1.1 Have the basis for the values and the input parameters used for each exposure scenario been established?

3.1.1.1 If based on actual data, has the quality, purpose, and representativeness of the database been addressed? Are all pathways supported with data?

3.1.1.2 If based on assumptions or defaults, is the source and general logic of the assumptions been described?

3.1.1.3 Are site concentrations sufficiently different from background?

3.1.1.4 If based on analytical results, were quality assurance practices followed and documented? Was the strategy of collection and the number of samples appropriate?

3.1.2 Have the exposure factors (e.g., concentrations, body uptake, duration/frequency) thought to be most critical for uncertainty in the exposure estimate been identified and addressed? Has sensitivity analysis been done to define these critical exposure factors? Have the uncertainties in the physical setting and the selected exposure assessment model been assessed for site specific conditions and parameters?

3.1.3 Have the individual of central tendency and high risk end individual been identified and reported with an exposure assessment and risk estimate?

3.1.4 Have important subgroups of population such as highly exposed or highly susceptible groups been identified and reported with an exposure assessment and risk estimate?

3.1.5 Has information about impact of possible low probability but possible high consequence events been addressed?

3.1.6 For the population risk:

3.1.6.1 Are the number of cases of a specific adverse health effects been probabilistically estimated for the specific period of time?

3.1.6.2 For non-carcinogens, are the portion of the population that is within a specified range of the benchmark level addressed?

3.1.6.3 For carcinogens, are the number of people exposed about a specified risk level included?

4.0 Risk Characterization

4.1 What do the risk assessors, risk managers, and the public need to understand about key conclusions? Are the assumptions included and is there balance between the confidence and uncertainty?

4.1.1 Are the numerical estimates of risk tied to narrative to aid the decision-makers with complete characterization?

4.1.2 Are the key assumptions and critical qualitative uncertainties of all the risk assessment steps noted in the narrative?

4.1.3 If alternative options for addressing uncertainty is considered, is the strength and weakness of the alternative approaches discussed? Is the rationale for the chosen option included?

4.1.4 The following points for risk characterization uncertainties were addressed in the EPA RAGS (1989a):

4.1.4.1 Are the key contaminants identified? Are the contaminant concentrations compared to background concentration ranges?

4.1.4.2 Is there a description of the cancer types or other adverse effects (e.g. liver toxicity, neurotoxicity) present at the site? Are these effects distinguished from known human effects versus predictions based on animal experiments?

4.1.4.3 Is there a level of confidence for the quantitative toxicity information used to estimate the risks? Is there a qualitative discussion on the toxicity of substances not included in the risk assessment?

4.1.4.4 Is there a level of confidence expressed for the key exposure pathways and the related exposure parameter assumptions?

4.1.4.5 Is there discussion of the major factors driving the site risk such as the substances, pathways and multiple pathways.

4.1.4.6 Are the major factors reducing the certainty in the results and the significance of these uncertainties (e.g., combining risks over several COCs or pathways) addressed?

4.1.4.7 Are exposed population characteristics addressed?

4.1.4.8 Is there comparison to any known site-specific health studies?

5.0 Uncertainty Factors in Noncancer Risk Assessment

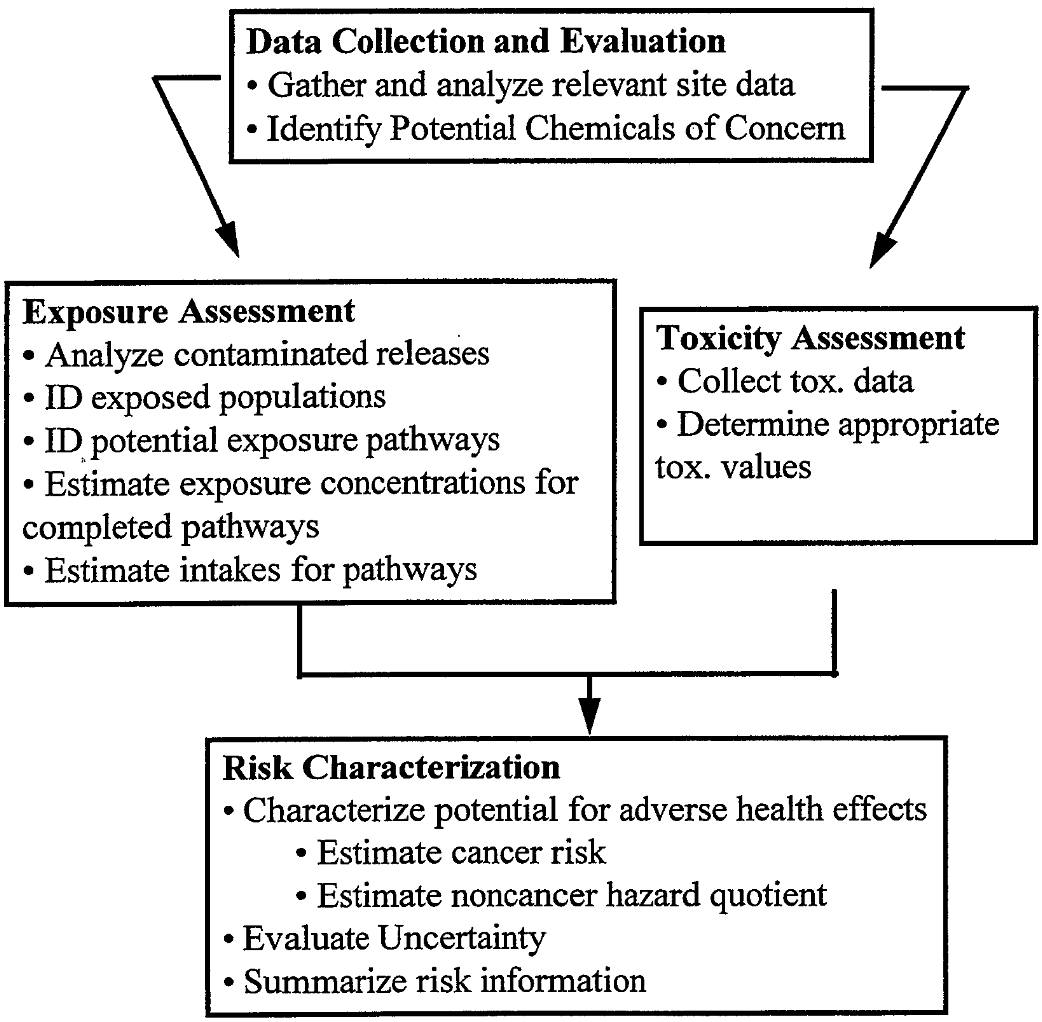
5.1 Dourson *et al.* (1996) reviewed the evolution of science-based uncertainty factors (UFs) in lieu of using default values. Table 2 presents a summary of their findings.

5.2 Probabilistic approaches can be used to establish a range of values for each uncertainty factor. Monte Carlo simulation can be used to develop an overall uncertainty distribution based on the distributions of the individual distributions (Dourson *et al.*, 1996).

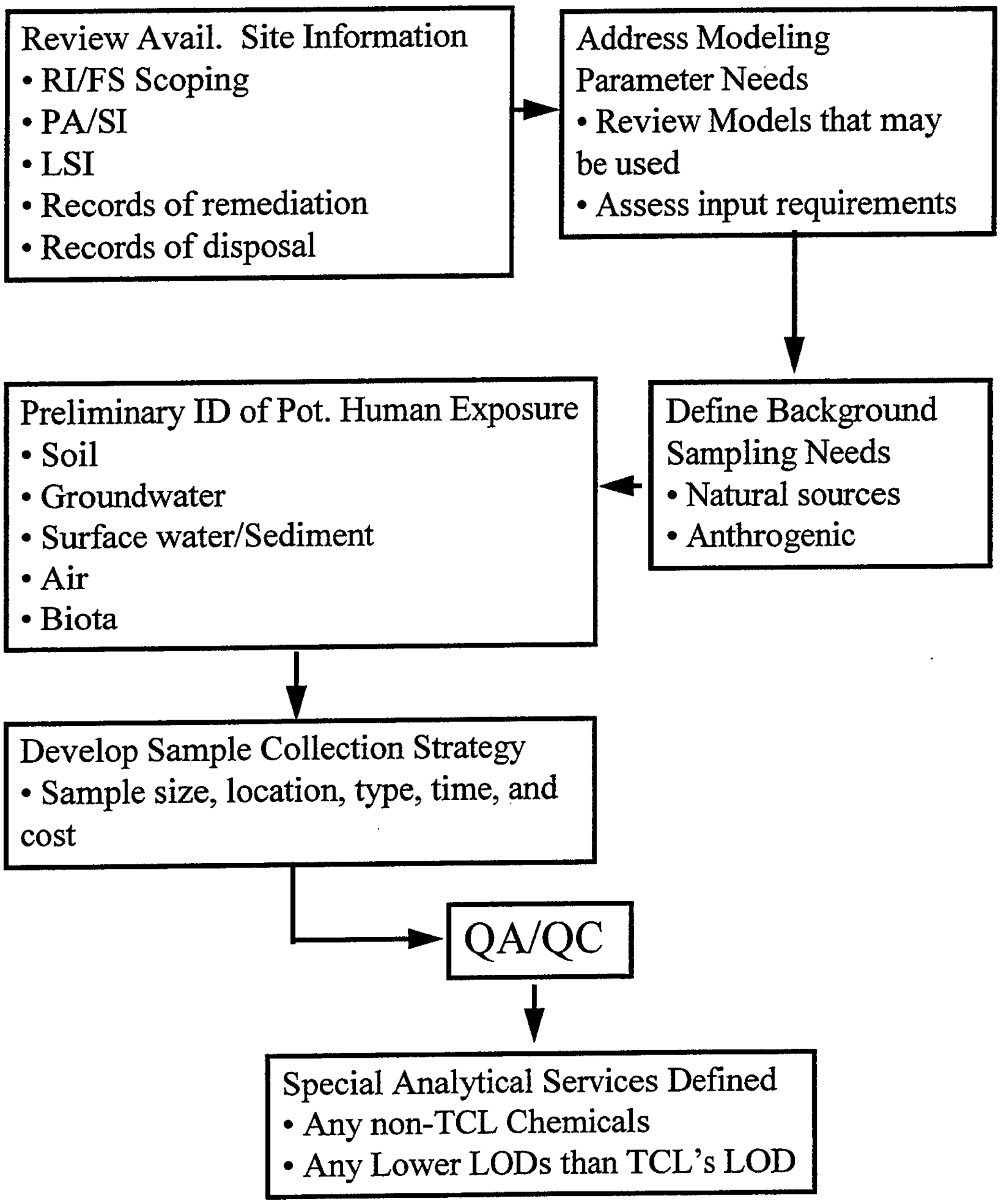
TABLE E-1: SUMMARY OF UNCERTAINTY FACTORS FOR NONCANCER RISK ASSESSMENT

Uncertainty Factor	Guideline	U.S. EPA Default	Science-Based Results
Interhuman or Intrahuman	Extrapolating from avg. human studies to account for human sensitivity variability	10	Default value appears protective but if sensitive subpop. NOAELs or toxicokinetics are known, adjust UF
Animal to Human	Extrapolating long term animal studies to human to account for toxicokinetics uncertainties	10	Propose PB-PK models to reduce toxicokinetics and toxicodynamics uncertainties, adjust UF
Subchronic to chronic	Extrapolating subchronic NOAELs or LOAELs to chronic NOAELs or LOAELs	≤ 10	Avg. ratio by investigators was 2-3. Default value is a loose upper-bound estimate
Incomplete Data base	Incomplete animal studies results	≤ 10	Need more than 1 study to est. sub-threshold dose, data missing, need UF, more research needed to quantify this UF

Baseline Human Health Risk Assessment Overview



Data Collection



Data Collection Continued

Contribute to Workplan Development
- Present needs at scoping meeting
- Contribute to Workplan
- Review sampling & analysis plan

↓

Data Evaluation

- Combine data from site investigation
- Evaluate Analytical Methods needed
- Establish quantitation limits
- Evaluate qualified and coded data
- Evaluate Tentatively Identified Compounds (TICs)
- Compare blanks and sample concentrations
- Develop a set of chemical data and information
- Identify Chemicals of Potential Concern (COPCs)

Exposure Assessment

Characterize Exposure Setting
• Physical setting
• Potentially exposed populations and subpopulations
• Determine current and future land use

↓

Identify exposure pathways
• Sources and receiving media
• Fate & Transport evaluation in release media
• ID exposure points and exposure routes
• Assess first three steps for complete pathways
• Summary information on complete exposure pathways

Quantify exposure
• Estimate exposure concentrations
• For specified pathways, estimate intakes
• Quantify the Reasonable Maximum Exposure (RME) function of exp. conc., cont. rate, exp freq. & duration, body weight and averaging time

Determine exposure concentration
• Monitoring data
• Modeling output to fill spatial and temporal gaps
• Maps of activities Vs conc. distributions - overlay reveals exposure areas
• Coordinate specific F &T models with RPM